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CANCER: CHALLENGES AND OPPORTUNITIES IN THE 21ST CENTURY

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

ON

EXAMINING CANCER RELATING TO CHALLENGES AND OPPORTUNITIES IN THE 21ST CENTURY

MAY 8, 2008

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STATEMENTS

THURSDAY, MAY 8, 2008

ADDITIONAL MATERIAL

CANCER: CHALLENGES AND OPPORTUNITIES IN THE 21ST CENTURY

THURSDAY, MAY 8, 2008

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 9:04 a.m. in Room SH–216, Hart Senate Office Building, Hon. Edward M. Kennedy, chairman of the committee, presiding.

Present: Senators Kennedy, Dodd, Harkin, Murray, Reed, Brown, Burr, and Murkowski.

Also Present: Senator Hutchison.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. Well, there are many important hearings that are taking place in the U.S. Congress probably this year. I think, for many of us on this committee, this really is one of the most important.

Not only is it related to something that families across this country are concerned about, but we also have three very extraordinary individuals in our first panel, others that will follow who really represent the best in terms of knowledge and understanding and commitment on this issue. So today is a very special day for our committee and for many of us on this committee who had a long-time interest and association with trying to deal with the challenges of cancer.

I will make a brief opening statement. I will ask Senator Murkowski if she would make a brief opening statement. We have some time issues, then we will listen to, hear from our witnesses.

We are honored today to have such distinguished guests. We welcome Elizabeth Edwards, a dear friend. My wife, Vicki, and I have enjoyed the times that we have spent with Elizabeth, John, and the Edwards family. Elizabeth is currently an inspiration to me, and I know she is for millions of Americans, as she shares with the Nation her spirit of determination, her hope, optimism, and we admire her very much.

We also welcome Lance Armstrong. America cheered you on to seven Tour de France victories, cheered you in your battle with cancer. Now you are doing the cheerleading, urging us to do all we can to find the cure.

We are honored to welcome Steve Case. We know that he was a pioneer at AOL and in our transition to a high-tech economy.

Today, he has dedicated those same talents and extraordinary abilities to fight against cancer.

So each one comes to this issue from different paths, with a variety of experiences and insights to offer, but we have a common commitment to do all we can to stand with those facing cancer and to find a cure. So I thank you all for the enormous difference you are making on this issue and for being with us today.

Thirty-seven years ago, a Republican president and a Democratic Congress came together in a new commitment to find a cure for cancer. At the time, cancer was the second-leading cause of death in the Nation. Americans lived in fear that they or someone they loved would be lost to this dreadful disease.

In 1971, in response to these serious concerns, we passed the National Cancer Act with broad bipartisan support and launched the war on cancer. Since then, significant progress has been made. New methods to prevent and treat cancer have led to more beneficial and more humane ways of dealing with the illness.

The expansion of basic research, the use of large-scale clinical trials, the development of new drugs, and the enhanced focus on early detection have led to breakthroughs unimaginable only a generation ago. And as a result, today cancer is no longer the automatic death sentence that it was a generation ago.

But despite the impressive achievements in fighting cancer, our society now faces a perfect storm of conditions, have expanded the number of our citizens suffering from cancer—the aging of our population, the new environmental issues, increased life expectancy, and unhealthy behavior. As a result, today cancer is still the second-highest cause of death in America.

Clearly, we need a new way forward in battling this frightening disease. We must build on what the Nation has already accomplished and launch a new war on cancer for the 21st century. We stand on the threshold of unprecedented new advances in life sciences, such as much earlier diagnosis based on molecular evidence and astonishing new treatments tailored to an individual's own DNA and capable of blocking the gene's effects.

To make the promise of this new century of discovery a reality, we must see the patients' DNA tests are free from any fear that their genetic information will be used against them to deny them health insurance or even jobs. Congress took a major step last month towards unlocking the potential of this new era of approving comprehensive protections against genetic discrimination in health insurance and employment, and President Bush is about to sign it into law.

To launch this new war on cancer, we must first give new urgency to efforts to find cures for cancer. We have learned over the years that cancer is, in fact, not a single disease. Knowledge gained from molecular biology now suggests that cancers vary not only from type to type, but from person to person, with each individual having specific cancer that is at least partially unique.

Second, an equal priority must be to lift the horizons of science to detect and prevent the disease before it develops. We can now look at each other's genes to prevent cancers before they happen. We can tap modern technologies that can detect and destroy cancer cells in their earliest stages before they destroy a life. We can con-

tinue to work on vaccines that will eradicate a threat over a lifetime.

Third, we can treat patients with modern therapies that enable them to survive their cancers and lead full lives. Modern medicine allows individualized care for the specific biological, social, and emotional needs of each affected person.

And finally, we need to integrate our current fragmented and piecemeal system of addressing cancer. Front and center in our current system are the troubling divisions that separate research, prevention, and treatment. Our current system treats these three aspects of cancer care as being inherently separate, rather than what they really are—different aspects in the continuum of comprehensive cancer care. The net effect of this fragmentation is the development of marked disparities in research, market innovation, and access to care and quality of care.

In sum, we need an entirely new model—for research, prevention, for treatment, and we are here today to begin that effort. We must move from a "magic bullet" approach to a mosaic of care in which advance becomes part of a larger picture of cancer care.

We have today an esteemed group of witnesses to start what I hope will be an ongoing conversation on cancer in our Nation and the world.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. We are joined, I see, by Senator Hutchison, and we are delighted to welcome our principal co-sponsor of this legislation. Someone who has been enormously involved and active in this and many other health issues, and we are delighted.

STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Mr. Chairman, I want to thank you. I want to thank Senator Enzi for scheduling this hearing this morning.

I want to welcome those on our first panel. Clearly, a very, very distinguished panel, leaders in this area, and we appreciate all that you do and your efforts on behalf of those afflicted with cancer and your efforts to make sure that we win this battle.

Mr. Chairman, you mentioned the war on cancer that was launched by President Nixon back in 1971. That was a long time ago, 36 years ago. It has been about $79 billion ago. And the war on cancer continues.

We are very, very proud, and we are very thankful for the more than 10 million cancer survivors nationwide. The great researchers, the great scientists that have helped us achieve progress in many, many areas. But as we all know, the war continues.

Cancer accounts for one in four deaths in the United States. But we do know that we have seen some good news. We have seen some progress. Researchers have made impressive strides in battling certain types of cancers. It is estimated that 99 percent of prostate cancer patients will survive at least 5 years, and 9 out of 10 breast cancer patients will, too. This is compared to about a 70 percent rate for prostate cancer, 75 percent for breast cancer back in the mid-1970s.

We are making gains. We have come a long way. I think we all acknowledge that there is so much more to do.

Those of us on the HELP Committee, quite frequently say, "an ounce of prevention is worth a pound of cure." I believe very strongly that education on the cause, the risks of those factors—whether it is tobacco use, alcohol—looking at what it is that we can do to outreach, to focus on prevention, to help motivate and enable individuals to get screened for cancer early, to make healthy lifestyle choices.

You look at Lance Armstrong here in the middle. Talk about healthy lifestyle choices, and yet, cancer comes along. We recognize that with a limited exception of pap tests, mammograms, pelvic and colorectal and prostate exams, Medicare and most State Medicaid programs do not cover preventive and screening services for cancer. This is unfortunate because we do recognize that there are relatively low-cost screenings.

In the State of Alaska, where so many of our Alaska Natives are afflicted with oral cancer, we know that early and lower-cost screenings could greatly improve the early diagnosis and dramatically increase a patient's chance for survival.

Now, while our cancer research is yielding significant improvements in the diagnosis, in the treatment, and the prevention of many forms of the disease, we have to appreciate that Federal funding for cancer research is not doing what we need. It is declining. And we cannot forget the advances that have been made and then the years that it takes for the drug developments to occur.

We certainly recognize this in the drug Herceptin that is used in the treatment of the "Her-2 positive" form of breast cancer. Initial discovery was made in 1979, and it wasn't until 1998 that Herceptin was approved by the FDA for use in breast cancer patients. We can and we must continue to bring the life-saving drugs to market to build on the progress that we know.

I want to specifically mention the Lance Armstrong Foundation and some of the specific efforts that we have seen in Alaska. You have helped us in an outreach to our Alaska Native communities by funding the "Traditional Food Guide for Alaska Native Cancer Survivors." This is a full-color 142-page nutrition guide that has been published by the Alaska Native Tribal Health Consortium cancer program, and it highlights the traditional foods that should be eaten by cancer patients.

Keep in mind that the high rate of cancer that we are seeing amongst Alaska Natives, are out in villages. You have access to some of the food that you see in the grocery store, but a lot of it is the traditional subsistence food. Are the berries safe? Is this type of fish safe or not safe? What part of the moose do you eat?

I learned in this guide that the nose of the moose is OK, but the lips are not where you should be going if you have cancer. We appreciate that the Lance Armstrong Foundation has helped us with this food guide. We understand that the first order of 3,000 copies has already been distributed and completely gone. We appreciate your help with that.

I also want to make sure that I recognize the important work that tens of thousands of volunteers do every day at national and State organizations, such as the Susan G. Komen Foundation, the American Cancer Society, the Lance Armstrong Foundation. These are all critical to us as we fight the war against cancer.

We all know someone that has been impacted by cancer in some way. We have lost too many loved ones to not ensure that NIH and NCI have the funding necessary to find the cure for all of these diseases.

Again, I thank you, Mr. Chairman, for your leadership in this. Senator Hutchison, for yours. I look forward to the comments from the very distinguished panel.

The CHAIRMAN. Senator Hutchison, we thank you for being here and welcome a comment from you.

STATEMENT OF SENATOR HUTCHISON

Senator HUTCHISON. Thank you very much, Mr. Chairman and all of the members here.

I just want to say a few things. First, I will be anxious, Lance, to see the Texas version of nutritional eating for cancer survivors and what parts of the armadillo——

Mr. ARMSTRONG. No, the longhorn. You should not eat the horns on the longhorn.

Senator HUTCHISON. Thank you very much. I was hoping that you would——

Mr. ARMSTRONG. But, I am not even a nutritionist.

[Laughter.]

Senator HUTCHISON. Let me just say a couple of things. First of all, I am so pleased and honored to join with Senator Kennedy in the initiative that will look at where we are. I think that Senator Kennedy and Senator Murkowski have covered some of the major reasons why we are here. I think it is time for us to step back from what Congress has already done, and that is double the NIH funding with, I might say, great help from Senator Harkin, who is at this table. It was Senator Harkin and Senator Specter who led the way for the doubling of the funding for NIH, and I thank you for that.

I was one of the 25 or so women who sat in Nancy Brinker's living room back in the, I guess, early 1980s that became the foundation for the Susan G. Komen Foundation. I have worked on and followed the progress on breast cancer research for a long time, and I am pleased that Hala Moddelmog from the foundation is going to be one of the witnesses today.

I want to also say that my brother has multiple myeloma. I have also championed the blood diseases, and I know about the progress and what isn't being done in that field.

I have watched Elizabeth Edwards be such a great role model for America, the way you have accepted and kept a smile on your face, she's just been the most amazing person going through the treatment at the time. It is an inspiration for all of us.

And Lance Armstrong, oh my gosh. You know, I want to say that Lance Armstrong—of course, I am proud that he is a Texan. To have been the inspiration to cancer survivors that he is, to show that not only can you survive cancer, but you can become the best in your field in sports in the world, and you can do it six times——

Mr. ARMSTRONG. Seven.

[Laughter.]

Senator HUTCHISON [continuing]. And be a cancer survivor. Seven? What? Seven. Oh, I underestimate you all the time, Lance. Seven times he can be the world champion.

What I love the most is that he has now taken on a new effort. He led the effort in Texas to pass a $3 billion bond issue just for cancer research and treatment, and he could have rested on his laurels. He could have gone to Hollywood, or I guess he wouldn't be going to France again. But he is doing even more to say that we can beat this if we just keep working.

He has led the effort for the bond issue, which we are now going to begin to process, doing things like Lisa mentioned in Alaska. It is beyond what anyone could have ever hoped for, and I am so proud to be here with you and to lead this effort with Senator Kennedy.

Let me just say that what Senator Kennedy and I are going to do, and this hearing is going to be a big part of it, is try to remove the barriers that we see today. We know that there could be more progress and coordination in cancer research, that there is so much going on, but it is not being coordinated well enough to produce the results that we need.

We need to reduce the disparities in cancer treatment because we know there are certain sectors of our country that are being under-treated maybe because they don't have access to the early detection and prevention knowledge. We want to make sure that we are doing that.

Enrollment in clinical trials, making sure that those clinical trials are covered by insurance. This is going to be what I think we are going to be looking at.

We look forward to hearing from the witnesses on both panels. I will have to be leaving, but I will be coming back and listening throughout the testimony because we are going to renew our war on cancer. And I look forward to the Kennedy-Hutchison bill, and we are going to make this happen.

Thank you very much.

The CHAIRMAN. Thank you very much.

We had planned to move ahead because we have scheduling issues, but I see my colleagues. If I could ask them to keep it less than 2 minutes and urge a word from Tom Harkin, who has, as Senator Hutchison, been such a leader in this whole area.

Would that be good? A couple of minutes should be about it. Hopefully, none of our other colleagues will come in, and we won't tell them if they do come on in.

Tom, thank you.

STATEMENT OF SENATOR HARKIN

Senator HARKIN. Mr. Chairman, thank you very much for your kind words, and Senator Hutchison. I just want to thank our panel.

I will just ask that my statement be made a part of the record.

[The prepared statement of Senator Harkin follows:]

PREPARED STATEMENT OF SENATOR HARKIN

I thank the chairman for calling this important hearing. And I want, in particular to welcome my friends Elizabeth Edwards and Lance Armstrong to the committee.

Elizabeth, in addition to being an outstanding advocate for screening and early detection, you have set an amazing example for every person fighting cancer—an example of courage, tenacity, and a truly indomitable spirit. We thank you for coming, today.

Lance, you became a national *hero* for winning the Tour de France 7 years in a row. You have become a national *treasure* as America's No. 1 advocate for cancer research, detection, and treatment. I want to thank you, again, for testifying at my cancer field hearing in Iowa City in July 2006.

I have been very pleased to secure funding every year since 2004 for a unique partnership between the Lance Armstrong Foundation and the Centers for Disease Control and Prevention. That partnership has resulted in the National Action Plan for Cancer Survivorship, which is charting the course for our entire Nation in how best to prevent secondary cancers and recurrence of cancer, and how to improve the quality of life for survivors.

This is personal with me. I have lost four of my five siblings to cancer. And, with better detection and screenings, perhaps my siblings would have had a better outcome.

I believe passionately in doing our best to *prevent* cancer, by encouraging appropriate lifestyle choices, including good nutrition and smoking cessation. I am equally passionate about the need to do a better job of detecting cancer as early as possible.

In 1990, I secured the first funding for the National Breast and Cervical Cancer Early Detection Program. And I've championed that funding every year since. It currently stands at $200 million annually.

In 2005, I secured funding for a Colorectal Cancer Screening Demonstration Program in five communities around the country. Colorectal cancer is the second most deadly form of cancer, killing nearly 55,000 Americans each year. We know that screening is extremely effective: you detect polyps and remove them, and this dramatically reduces the risk of this type of cancer.

The Colorectal Cancer Screening Demonstration Program has been a huge success on a small scale. This year, I intend to make this demonstration program *permanent*, and to double its reach in the coming year.

Of course, the biggest issue with regard to cancer prevention and research is *money*. Right now we are waging a war on cancer on a shoestring budget. In truth, over the last 5 years, we have been funding a *retreat* in the war on cancer. And that is a national shame.

Between 1998 and 2003, Senator Arlen Specter and I teamed up to nearly double funding for the National Cancer Institute. Because of the President's misplaced priorities—funding the war in Iraq, not the war on cancer—National Cancer Institute funding has fallen short of biomedical inflation every year for the last 5 years. The President has proposed an increase of less than $5 million for 2009. As I said, that is simply shameful.

And, make no mistake, this kind of neglect has consequences.

At the National Cancer Institute, only 11 percent of research grants are being funded. This is the highest percentage of rejections in decades. They are rejecting many grants of exceptional quality. Projects seen as risky—even if they have great potential for breakthroughs—are much less likely to be funded.

We have got to do better.

We need a surge in the war on cancer.

We need a surge in funding for screening and prevention.

We need a surge in embryonic stem cell research relevant to cancer.

I intend to do everything I can to increase funding this year. And I agree wholeheartedly with Lance Armstrong: Cancer funding should be an issue in the election this year. We need to know where every candidate for President and Congress stands on the issue of funding the war on cancer.

Senator HARKIN. I just want to thank our panelists for their courage, their tenacity, and the example that they show everyone on how to fight cancer and that indomitable spirit that the two of you have. Also, for Mr. Case, in challenging accepted ways of thinking and trying to get us to think differently about how we do some of these things.

So, all three of you, thank you very much for your leadership in this area.

The CHAIRMAN. Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, I will join my colleague, Mr. Harkin, and be brief. I want to welcome Mrs. Edwards, who is a great advocate for healthcare from North Carolina. We welcome you here today. Lance Armstrong, who is just a fabulous athlete and a great spokesperson. And Steve Case, an unbelievably successful business person.

I want to encourage my colleagues if you haven't read in detail Steve Case's testimony, I would ask you to do so. I just want to read one part that I think really hits home.

> "The policies now in place limit collaboration and slow innovation by making it difficult for NCI to partner with for-profit companies."

This identifies an absolute key that we have got to figure out, and Steve, I just want to thank you for your testimony. It is very out-of-the-box compared to how we think in Washington, and I encourage my colleagues to pay particular attention to his statement.

I thank all three of you for being here.

The CHAIRMAN. Thank you very much.

Senator Brown.

STATEMENT OF SENATOR BROWN

Senator BROWN. Thank you, Mr. Chairman, and thanks to all three of you on the panel, especially to Elizabeth Edwards. Your op-ed in the *New York Times* recently was just phenomenal. My wife, who is a terrific admirer of yours, as you know, sends her regards.

A couple of real quick issues that Senator Hutchison touched on in the health disparity issue. The death rate for African-American men from prostate cancer is 240 percent higher than it is for white men. African-American women have a lower incidence of breast cancer than white women but are more likely to die of the disease.

We know these health disparities are so, so serious. That is a big part of what Senator Kennedy's bill needs to address and will address.

Another issue, and real briefly, I am introducing legislation this week called the Access To Cancer Clinical Trials Act. I have found out in a series of roundtables I have done around Ohio in the last year-plus that an insurer—you will buy an insurance policy to insure yourself on the premise that the policy covers medically necessary routine care. Then you enroll in a clinical trial. Suddenly, your insurer refuses to cover your routine healthcare costs while you are in the clinical trial.

In essence, you are in a clinical trial. They drop the coverage you have for the rest of your standard care, which is quite a disincentive to enroll in a clinical trial, which obviously threatens your own health too often as a cancer patient and sets back medical science. It is something that clearly we need to fix. That is a small part of the efforts we need to put forward with something we should do.

Mr. Armstrong, thank you. Mr. Case, nice to see you. And thank you, Elizabeth.

[The prepared statement of Senator Brown follows:]

PREPARED STATEMENT OF SENATOR BROWN

Thank you, Mr. Chairman, for focusing on convening this important hearing.

In one way or another, cancer has touched all of our lives. A loved one, a neighbor, a friend, a role model . . . someone we know is fighting cancer.

As it stands, cancer is a vicious enemy, a brutal fact of life.

We are making progress, and someday we will put cancer in its place. We will prevent it and we will cure it.

Medical research is the lynchpin. And needless barriers to research are a deadly setback.

I'm introducing legislation today that confronts one of those barriers: unjustifiable out-of-pocket costs.

Here's what happens: An insurer sells you a policy on the premise that the policy covers medically necessary routine care. Virtually all health plans do.

Then you enroll in a clinical trial.

Suddenly, your insurer refuses to cover routine health care costs, even if those costs have nothing to do with the clinical trial itself.

It deters people from enrolling in clinical trials, which thwarts medical research and chokes off hope for patients who have exhausted all their other options.

I am introducing the Access to Cancer Clinical Trials Act to prevent insurers from establishing illogical, unethical, *insupportable* coverage exclusions for routine care . . . care that is not associated with a clinical trial, but that happens to coincide with it.

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This bill is a true Ohio effort—Ohio Congresswoman Debra Pryce, a leader in the area of cancer research, has championed this legislation in the House.

I am introducing the Senate companion to advance her vision and pave the way for more cancer clinical trials.

Our bill obligates health plans to pay for routine care costs when a cancer patient enrolls in a clinical trial.

These are costs that would normally be covered if a cancer patient were not participating.

The legislation is very specific in its definition of routine care costs to make it clear that clinical trial-related care would still be covered by the trial itself, as would the costs of any complications related to the trial.

It is equally clear in stopping health plans from treating cancer patients like second class citizens, dashing their hopes and compromising the public health.

Last year, Sheryl Freeman and her husband, Craig, of Dayton, OH, visited my office in Washington, DC.

Sheryl had multiple myloma. Sheryl and Craig brought to my attention the problems they were having with their insurance company.

Sheryl was a retired school teacher and was covered under Craig's insurance plan.

Craig has been a Federal employee for 20 years and has one of the best health plans in the country.

Yet when Sheryl tried to enroll in a clinical trial, her insurance company would not cover the routine costs of her care.

In addition to her clinical trial in Columbus, Sheryl needed to visit her oncologist in Dayton at least once a week for standard cancer monitoring, which included scans and blood tests.

But her insurance company would not cover these services if she enrolled in a clinical trial.

Sheryl wanted to take part in a clinical trial because she hoped it would help her. She hoped that it might save her life, give her more time, or advance cancer research.

Rather than devoting her energy toward combating cancer, Sheryl spent the last months of her life haggling with her insurance company.

The delays and denials from Sheryl's insurance company probably affected her treatment and her survival.

Sheryl died on December 9 of last year. This story should have ended differently.

Sheryl and Craig should not have had to sacrifice their precious time together trying to get the care she deserved, the care she paid for when she signed up for health insurance.

On Monday of this week, I met another cancer patient, Merle Farnsworth, from Beverly, OH.

Merle has lymphoma. For him, clinical trials signify hope. Hope for the future, hope for others who are fighting cancer, hope for a cure.

As we take a closer look at cancer today, I will be thinking of Merle and Sheryl. No one should be robbed of hope by an insurance loophole. No one.

Thank you, Mr. Chairman.

The CHAIRMAN. We will ask Elizabeth Edwards if she would lead off. There are many parts of your biography, all of your biography was left out. One additional part that I will add for Elizabeth Edwards is that tonight she has been—will celebrate being elected as the recipient of the Mother of the Year award.

[Applause.]

The CHAIRMAN. So, congratulations to you on that as well.

STATEMENT OF ELIZABETH EDWARDS, J.D., SENIOR FELLOW, CENTER FOR AMERICAN PROGRESS, WASHINGTON, DC

Mrs. EDWARDS. Thank you all. Thank you to Senator Enzi, who is not here, for this hearing; to Senator Kennedy for your role not just today, but, of course, for decades in being a leader on these issues; Senator Murkowski for your interest in it; and Senator Hutchison for your co-sponsorship of this bill—or I guess sponsorship of this bill is enormously important. Senator Harkin, obviously an enormous voice with respect to all sorts of healthcare issues.

I want to tell a story before I begin that actually involves Connie Schultz, Senator Brown's wife. I was in Cleveland in March 2007, giving a speech at a luncheon, and Connie was there. It was a very nice event.

Afterwards, a number of people spoke to me. One woman who was very well-dressed, leaned over, spoke to me and said, whispered in my ear—she didn't want anyone to hear—whispered in my ear that she had a lump in her breast. She was really afraid for herself and for her children because she had no health insurance and, therefore, could not get it tested.

We tried—she ran off before—I guess to get back to work before we were able to hook her and Connie up so that she could get the treatment and the great services that they have in Cleveland and make certain that that one gap was filled.

It says some bad things about us, of course, that we have a system where a working mother can't get healthcare that she is going to need in order to be able to continue to provide for those children. It also says something kind of good about our spirit, I think. That this woman, despite all of the hurdles that she had in front of her, believed that if she just whispered in the right person's ear, something could change.

Since March 2007 and hearing that woman's whisper in my ear, I have been trying, and this is—I want to thank you so much for giving me the opportunity now to whisper for her in the right person's ears. Those are your ears because you have the capacity to make a difference in the life of that woman and so many women who are like her.

I speak a lot about healthcare policy now. I am a senior fellow with the Center for American Progress. This is an issue that doesn't know political boundaries. It knows moral boundaries, and we have an obligation as human beings, to make certain that we answer this call.

Senator Murkowski said one in four Americans dies of cancer, one in four of us. If you look around the room and imagine how many of us that is, it is a necessity that we respond to this demand. The fact that it is nonpartisan is indicated by the fact that

the first war on cancer was led by President Nixon with a Democratic Congress, all believing we needed to respond.

Believe me, in addition to my occupation, I also, of course, am—I have metastatic breast cancer. It will undoubtedly be the reason that I die, when I do. I have a real interest in the treatments and making certain that those happen. Making certain that we pay attention to metastasis in our research as an important part of the process, the part of the process that usually takes us, when it does.

I want to talk today about the fact that it doesn't matter what kind of services we have if we don't have access to them. And the impediments to access are often—or some of them are whether or not we have insurance. Some of them are demographic, our economic status. Some of them are geographic. If we live in rural areas, it is more difficult for us to get services. These are things that need to be addressed.

I want to make three points in my testimony today. One is that health insurance matters. The quality of coverage, of course, matters. Health insurance itself is really a crucial part of this. Probably the most preventable cause of unnecessary suffering in our healthcare system is the lack of adequate health insurance. That was what this woman was complaining to me about.

Compared to those with health insurance, uninsured people with cancer are more likely to be diagnosed late, less likely to have access to needed care, and more likely to die within the 5-year period. They are also less likely to have their lives prolonged. It is likely to be tied to the ability to get access, both demographically and geographically.

As Senator Brown was mentioning these disparities, if you are a black woman today—we have made all this progress that we have been talking about, which is great. If you were a black woman in 1988, your chances of survival were essentially the same as they are today if you have advanced breast cancer. They haven't changed in 20 years. Now if you are a white woman, they have changed. You have a chance of living about 2 years longer because of the improvements that have been made because of the research. These are not available widely.

I have a friend. You must know I am a North Carolinian, right?

There are, of course, right and wrong ways to insure us. It is really important that we build, I think, and I hope that your programs will build on the existing successful system of employer-based coverage until we are able to subsidize everybody. I hope that there would be a someday when we are able to do that, but until we do, what has worked for us is an employer-based system. We need to make certain that that remains in place.

Because people who are uninsured—47 million of us are uninsured, another 15 million or so who are underinsured—are largely uninsured because we don't have coverage through our employer.

Among those 47 million who are uninsured, a million have cancer. And they are the ones we know about. Obviously, there are a lot of them who are not getting diagnosed. Assume if you have a one in four chance of getting cancer, you are probably talking more about 12 million of them, who will eventually die of cancer if they do not get the treatment that they need and some if they do.

Anyway, so we want to build on it. People should have the option of keeping that coverage if they want. Also from choosing from private plans, individual private plans, if that is what they choose to do. I would like them to have the quality of the services available to Members of Congress. I know that when my husband was in the Senate, served on this committee, I was afforded very good coverage. Which meant that although I had to be very afraid of having cancer, I didn't have to be afraid of not being insured.

Also, I would like to see us build on our public health system. You were talking earlier, Senator Murkowski, about Medicare and Medicaid and the need to make certain that these systems provide the kind of comprehensive coverage that we need. Short of comprehensive insurance reform, we also need to make certain that we are bolstering those public health systems and the policies, the insurance that is available through those, and filling the gaps in eligibility and in screenings and other kind of coverage, which currently exist in those systems.

We know how to lengthen and improve the lives of people with cancer, but we've chosen, as a Nation, to turn our backs on some of us who have the disease. I urge you to reform healthcare responsibly and morally and aggressively and save millions of us. Save that woman in Cleveland who whispered in my ear.

Thank you.

The CHAIRMAN. Very good. Thank you very much.

Mr. Armstrong.

STATEMENT OF LANCE ARMSTRONG, CHAIRMAN AND FOUNDER, LANCE ARMSTRONG FOUNDATION, AUSTIN, TX

Mr. ARMSTRONG. Thank you all. Thank you for having all of us here. Senator Kennedy, Senator Hutchison, Senator Murkowski, thank you. And to the other Senators as well, thank you.

My journey to this place began 11 years ago, when, for those of you who don't know, I was diagnosed with advanced testicular cancer that had spread throughout my body—the abdomen, the lungs, and the brain. It was obviously a surprise to me at the time because I assumed that I was a healthy, fit person, and I had never even had a broken bone, tendonitis. A common cold was very rare for me.

Then, all of a sudden, this happened and really turned my life upside down. Of course, it ended up being a bit of a blessing in that it gave me a new sense of perspective on my life. It became my life's work, and it became my life's mission to make sure that this disease is diminished in our lifetime.

I was fortunate enough in 2002 to be appointed by President Bush to the President's Cancer Panel and to serve 6 years and to listen to testimony from doctors and researchers and nurses and survivors and family members all over the world. And listen to their stories, listen to their passion. It taught me a lot.

This issue is big, and this issue is complicated. This issue, as we will talk about today, is literally hundreds of diseases. This is not one disease. I think America in general has this perception that let us just go and cure cancer. When, in fact, why am I sitting here today as somebody who feels like he has been cured, meanwhile down the street, a 45-year-old man will die of colon cancer? Be-

cause it is a different disease, and it is treated differently and operated on differently and monitored differently and researched differently.

We have to be realistic. The numbers are stunning. Five hundred sixty-thousand Americans die every year, 1 American every minute, 1.4 million Americans diagnosed every year, 12 million Americans living with cancer in this country today. Those are big numbers.

In fact, if you consider where does this disease rank, why are we talking about this? Well, we are talking about it because it is the No. 1 killer in this country for people under the age of 85, which says that it is worthwhile.

A couple of other things with regard to the scope of the disease is the economic impact of this illness. Today, in 2008, the economic impact of this disease is hundreds of billions of dollars on our society in terms of loss of productivity, loss of life, loss of efficiency.

It is projected that by the time—I have an 8-year-old son. It is projected that by the time he graduates college this disease will cost our society and our economy a trillion dollars every year. That is a number that, when compared to $6 billion or $7 billion in Federal funding at the NCI, seems to me to be out of line.

The other and, I think for me, the most important comparison here is the disparity in cancer care. Simply put, the 560,000 deaths that we have every year in this country, a full third of them could be prevented. We could save close to 200,000 American lives every year if we simply applied the information and the technology and the knowledge that we have to the people that need it the most.

To me, and I am not the smartest guy on this panel by any stretch of the imagination, but if we have something in-house and there is somebody down the street that needs it, and we are not walking down the street and giving it to him, we are failing. And so, I would also—I would stress that.

Having been around this fight for 10 or 11 years now, I have come to learn a thing or two, and I think the thing that sums it up for me the best is to discuss this epidemic as a continuum, what we call the cancer continuum. That, to me, really boils down to six areas, and those are prevention, screening and early detection, access to the best healthcare and medical care, scientific research, survivorship, and end-of-life care.

All of them have to be looked at when we talk about this issue, and I think that is what is so great about this new piece of legislation is that it really is a comprehensive look at the continuum. I mean, if it is prevention, we have to discuss tobacco and tobacco abuse. We have to discuss sun and sunscreen, et cetera, et cetera. We have to discuss other potential environmental factors, at least explore them.

Screening and early detection, we know—everybody in this room knows, I think, that the earlier you catch this disease, the better off you are. The chances for cure are so much higher.

Access to care, as I said, if we have the information and the technology and the science to cure people, regardless of the color of their skin, the neighborhood they live in, the language they speak, we should do that.

Scientific research, the fact that we have in the last few years been cutting the budget at the National Cancer Institute and the National Institutes of Health in the midst of a growing and oncoming epidemic, a perfect storm of an aging population, a sedentary youth population, and a disease that is really not going away, we are making a big mistake.

Survivorship—very, very important to understand that with 12 million of us living with this disease in this country, I fully understand what it means to be a survivor, and I also understand what it means to thrive after my disease. Making sure that I am aware and that everybody else, all 12 million of us, are aware of our future health risks, future potential side effects, secondary diagnoses, other potential problems. We have to make sure that anybody, especially for us, a cancer survivor maintains a high quality of life. And so, survivorship is important.

Ultimately and unfortunately, if somebody is going to pass away, that they pass with dignity and with pride and with the way that they want to go. Now, we don't ever want to end up there.

To close it up, I will tell a little story. I have been walking around these halls for almost a decade, probably close to a decade. And I have met with most of you guys and gals, and we have had, I think, some great success. I have got to tell you, the most poignant moment that I ever had, Mr. Kennedy, was when I was in your office. And we were discussing this very issue. And I never know if people are passionate about this or not because sometimes in DC that is the MO.

As we were discussing this issue, you started to talk about your son, and the next thing I know—and you sort of hesitated and you paused, and you got a little choked up, and I thought, "Oh, my God. Senator Kennedy is shedding a tear," and when he is talking about his son. You pointed to the picture on the wall, and there was Junior skiing down that slope. And you said, "That is my son, the cancer survivor."

I had the good fortune to meet your son last night, and it is an honor to have met him. It is an honor to be here with you to share your passion.

This is a major fight. This is a major war, and this is something, as I said, it doesn't care if you are a Republican or you are Democrat, if you are young or you are old, you are black or you are white, Native American, you are rich or you are poor. It comes, and it comes hard. It is ruthless and it is relentless.

And for us to win, we also have to be ruthless and relentless. I encourage all of us to do that. Renew the war on cancer. Renew a comprehensive war on cancer and ultimately make sure that our kids and our grandkids don't have to face this.

Thank you.

[The prepared statement of Mr. Armstrong follows:]

PREPARED STATEMENT OF LANCE ARMSTRONG

Mr. Chairman, members of the committee, thank you for inviting me to testify before the Senate Committee on Health, Education, Labor, and Pensions today. I am honored to be here with you. Chairman Kennedy, I applaud you and Senator Enzi for your leadership in renewing our Nation's focus on cancer.

Much has happened in the 37 years since Congress passed the National Cancer Act. Chairman Kennedy, I know you played a key role in the passage of that historic

legislation. Our National War on Cancer has made much progress since 1971. Thousands of lives have been saved and we have improved the lives of many more. Still, we can and must do better.

After I was diagnosed with cancer in 1996, I founded the Lance Armstrong Foundation (LAF), a 501(c)(3) national nonprofit organization based in Austin, TX. The LAF engages Americans to pursue an agenda focused on preventing cancer, ensuring access to screening and care, improving the quality of life for people affected by cancer, and investing in needed research. The LAF is committed to making cancer a national priority through our advocacy initiatives.

The facts are staggering. Five hundred and sixty-five thousand Americans will die of cancer in 2008—more than 1,500 people a day. One point four million Americans will hear the words, "you have cancer" this year. Cancer is already the leading cause of death for Americans under the age of 85, but it is certain to become the leading cause of death for all Americans in the next decade as the "Baby Boomer" generation ages.

I was honored to be asked by President Bush to serve two terms on the President's Cancer Panel. The Panel was established by the National Cancer Act of 1971 to monitor the development and execution of the activities of the National Cancer Program, and report directly to the President. Before my second term expired this year, I had the privilege of working with national cancer experts such as Dr. Harold Freeman, Dr. LaSalle Lefall and Dr. Margaret Kripke.

During my 6 years on the Panel, I contributed to the creation of four sets of recommendations to the President of which I am very proud. I feel that as much as I contributed, I've learned even more in the process. Traveling the country as a member of the Panel, I learned that as a Nation, we know what it takes to save lives. What we know and what we do are two different things.

Through my service on the President's Cancer Panel, I have seen first-hand the toll this disease takes on America and recognized it for the epidemic that it truly is. The recommendations made to the President by this Panel are ones that I stand behind and fully support. In fact, my foundation has made them cornerstones of our policy platform and our advocacy efforts. But sadly, one of my biggest frustrations throughout my service on the Panel is that very few of the recommendations we made ever came to fruition.

We have the ability and power to improve access to quality health care for cancer patients while lowering the personal costs of treatment. We can also cure many who have cancer and improve their quality of life.

Tragically, we do not use all available policy and regulatory tools at our disposal to optimize what we can control; nor do we deploy sufficient resources to stimulate scientific discovery and translation which hold enormous promise. Thanks to your leadership, we have an opportunity to renew our efforts in four key areas.

ACCESS TO CARE

Nearly 47 million Americans lack health insurance, and about 16 million more are underinsured. Study after study has shown that those who lack insurance or are underinsured have higher cancer mortality rates than those who have insurance and therefore better access to care. Healthcare coverage and financial concerns should not dictate who lives, who dies, and who suffers unnecessarily. Yet all too often, it does.

Quality cancer care means ensuring that people with cancer have access to treatment that has been proven successful and is appropriate. It means services are delivered in a patient-centered, timely, and technically competent manner. And, it depends on good communication and shared decisionmaking between the patient and provider in a culturally sensitive manner across the continuum of care and throughout the remainder of life. We do not take full advantage of what we already know about delivering high quality cancer care.

It is fundamentally and morally untenable that a world-class athlete who has been diagnosed with testicular cancer should have a better chance of surviving than an African-American resident of Harlem who has been given the exact same diagnosis. Yet minority and poor populations carry a disproportionate burden of the negligent cancer care in the United States—even when adjusting for socioeconomic factors.

QUALITY OF LIFE

We must improve the quality of life for people affected by cancer. Providing access to quality cancer care and improving quality of life are intertwined.

In 1971, there were 3 million cancer survivors in the United States. At that time, cancer was largely a death sentence. Today there are 12 million Americans living with the disease. Addressing the needs of this growing population is critical.

Quality of life means different things to different people. Broadly speaking, quality of life for those living with cancer may encompass physical well being, including symptom management; psychological and social issues; emotional well-being; and spiritual considerations.

Cancer survivors should be provided access to treatment summaries and survivorship care plans. Patients starting treatment should be provided written documentation that details all elements of their treatment and those completing primary treatment should be provided with a comprehensive care summary and follow-up plan that is clearly and effectively explained. These resources allow cancer survivors to play a critical role in their treatment decisions and provide much-needed documentation of their treatment history. This service should be uniformly reimbursed by third-party payors of health care.

Psychosocial support is absolutely critical to the quality of life of cancer patients and survivors, yet the healthcare system's provision thereof is often abysmal or nonexistent. We must ensure that clinicians incorporate psychosocial management as an integral part of treatment.

Cancer survivors are at increased risk of experiencing employment and insurance discrimination. Signing the Genetic Information Nondiscrimination Act (GINA) into law will go a long way to provide protections against the use of genetic information in health insurance coverage and employment decisions. Even with the passage of GINA, the fact that cancer survivors are consistently denied health coverage due to pre-existing condition classifications must also be addressed.

Pain management and palliative care for cancer patients and survivors is in need of improvement. Pain is the number one symptom cited in cancer as well as a host of other diseases, yet it is continually left under-treated. The appropriate management of severe symptoms such as pain, nausea and vomiting is not only central to quality of life, but it also has implications for the efficiency of the health care system.

CANCER MANAGEMENT

Managing cancer involves activities that aim to prevent or cure cancer and increase survival and enhance quality of life for those who develop the disease. We must deliver the knowledge we have gained through research into strategies and services to the general public.

We can have a measurable impact if we just apply what we know. We have the tools to detect many of the more common cancers earlier, when they are most treatable.

The U.S. Preventive Services Task Force (USPSTF) first recommended that Americans 50 and older be screened for colon cancer in 1996. If colorectal cancer is discovered early, before it has spread, the 5-year survival rate is 90 percent. If colorectal cancer is discovered after it has spread to distant parts of the body, only 10 percent of patients survive 5 years.

If all adults 50 and older were screened for colon cancer, we could save approximately 30,000 lives per year, cutting the death rate from this disease in half. Yet today, 12 years after the USPSTF first recommended this screen, we still have no Federal screening program for low-income and uninsured Americans.

Timely and regular mammography screening would prevent up to 30 percent of all deaths from breast cancer in women over the age of 40. Pap tests and the widespread use of the HPV vaccine can prevent virtually all deaths from cervical cancer.

Yet today, the National Breast and Cervical Cancer Early Detection program, administered by the Centers for Disease Control and Prevention, only reaches 20 percent of eligible women between the ages of 50–64 with current levels of funding.

We also need a unified and evidenced-based national cancer prevention and cessation campaign to reduce the use of tobacco products. Almost one out of every three cancer deaths in the United States—170,000 people a year—is the result of tobacco use. These deaths are entirely preventable.

RESEARCH

Simply applying what we already know about cancer prevention and early detection is not enough. For many Americans who die every day from terminal cancers, such as lung and pancreatic cancer, there is little known about how to effectively detect their disease early enough to decrease mortality.

For these people, research could provide the answer. We need to accelerate our investment in research on better detection methods for the deadliest cancers. We

must improve treatment options so they will only attack the cancer cells and reduce the overall damage to the patient. And we need to develop treatments to control and manage cancer, much as high cholesterol and heart disease are managed conditions today. This is all within the realm of medical science, but it will take a renewed and constant effort to become reality.

Unfortunately, our Nation's commitment to cancer research has fallen flat over the past few years. National Cancer Institute (NCI) funding for cancer research has been level since 2005. I applaud the Senate for taking a bold step by passing the Harkin-Specter amendment to the Budget in March, supporting a 10 percent increase in funding for the National Institutes of Health (NIH) for fiscal year 2009. It is my hope that this initial first step will allow Congress to get our national investment in biomedical research back on track through the appropriations process.

This is not a time when we should be decreasing our investment in extraordinary Federal research opportunities. Federal investments in cancer research have yielded remarkable results. Several drugs developed and/or tested by NIH-supported scientists have been proven effective in treating and sometimes preventing certain types of cancer. New, more precise ways to treat cancer are also emerging, such as drugs that target abnormal proteins in cancer cells and leave healthy tissue alone.

Investing more money in cancer research is necessary, but not sufficient. We must also use strategies that improve the incentives for scientists, restructure the enterprise to encourage collaborative team science, and support best practices and common sense in clinical trials and the translation of discoveries into practice.

The Federal Government faces significant challenges in coordinating research to improve cancer treatment, building effective cancer prevention programs, deploying quality cancer care delivery systems, and paying for quality care for cancer patients who depend on Federal health care programs.

In light of these challenges, we need a broad-based national cancer plan that aligns our research priorities with those for cancer prevention, early detection, treatment and survivorship. The NCI is doing great work in conducting cancer research, but our national plan must be broader than just cancer research. Too much knowledge sits on a shelf, never translated from the laboratory to the clinic. And effective evidence-based strategies for prevention and early detection remain underutilized costing America hundreds of thousands of lives.

Our national cancer plan should be a multi-disciplinary, cross agency approach that leverages the strengths of the various Federal agencies and remains accountable for developing results in comprehensive cancer control and care. Ultimately, we need strong leadership that responds to the needs of the American public, can implement the plan, is backed with the resources to achieve the goals, and has the authority to facilitate communication and collaboration across diverse Federal agencies that are engaged in cancer research, prevention, and care.

In 1999, after I won the Tour de France for the first time, I testified on Capitol Hill before the Joint Economic Committee about the promise of biotechnology. At that time, I indicated that I was a living example of what cancer research can do. If I had been diagnosed in 1971 rather than 1996, I would have likely died from the cancer that had invaded my body.

During that same hearing, my doctor, Dr. Larry Einhorn, testified that cancer was the scourge of the 20th century and if we don't accelerate our efforts, it will be the scourge of the 21st as well. Our national war against cancer has made some progress since I testified 9 years ago, but we still have a long way to go to eliminate suffering and death due to this disease.

It has been 37 years since the United States first declared war against cancer. I applaud the committee for your interest in renewing the fight against this disease and look forward to working with you, Senator Hutchison and other Members of Congress on this effort. We have new knowledge and new tools ready for deployment. And through your leadership, we can change the way our country is fighting cancer in the 21st century.

The CHAIRMAN. Good.

Mr. Case.

STATEMENT OF STEVE CASE, CHAIRMAN AND CEO, REVOLUTION HEALTH, WASHINGTON, DC

Mr. CASE. Well, first of all, it is a great honor to be here. Thank you for your leadership on this issue. I think your legislation is exactly the kind of thing that we need to bring a more innovative, collaborative, kind of out-of-the-box approach to this.

I am a little humbled to be on this panel with a world champion, a seven-time world champion. I am certainly not a world champion, and I am also certainly not Mother of the Year. I am just an entrepreneur, and I spent about 20 years just trying to make the Internet part of everyday life and try to usher in a more—a digital age. I must admit, for those 20 years, I didn't spend much time thinking about cancer. I was focused on all kinds of other issues.

I got a call at midnight 7 years ago from my brother, who had a diagnosis of a brain tumor and a week later was told that he probably only had about 6 months to live. We asked, the family, what causes this kind of tumor, and the answer was nobody really knows. And we asked what the treatment options were and people said, "Well, there really aren't any that have been particularly effective" and asked what the prognosis was. As I said, it was just sort of a death sentence.

He said, and we said, that is just not good enough. He was an investment banker and took a lot of companies like amazon.com and Electronic Arts and other public, and Silicon Valley, and said we need to bring an entrepreneurial technology-driven approach to bear here, and he started an organization, which carries on, called Accelerate Brain Cancer Cure, ABC2.org. It is focused on driving innovation, focused on driving collaboration, focused on more entrepreneurship in this field.

Coincidentally, this week, we have Brain Tumor Action Week. Sunday, we kicked it off with a Race for Hope down Pennsylvania Avenue, and I was joined by 8,000 other people talking about this issue and shining a spotlight on this issue and trying to raise additional funds for this issue.

I am not here to talk about brain cancer. Obviously, it is something I care deeply about. I think part of the problem we have now, 37 years into this war, is everybody is kind of focused on their particular silo, focused on their particular issue. What seems to be lacking, which is what I think your legislation is trying to address, is more strategic framework. Taking a step back and instead of looking at this as a series of little pieces of the puzzle, we should be integrating that puzzle in a more comprehensive, strategic framework.

That is really what I think is desperately needed. Coming at this relatively fresh. Bringing sort of an entrepreneurial approach. And certainly understanding technology and seeing how the Internet developed over the past few decades, it feels like that is what we need in this space.

The kind of leadership the Congress took with the Internet—in terms of some of the funding of DARPA and the flexibility it gave DARPA—because it desired to invest in this issue in the broadest possible context with the greatest level of flexibility because our national security was at risk.

Or when we set out with NASA to put a man on the moon, we said we need to do this quickly. We don't want to put a lot of restrictions on the groups focusing on this issue. We want to give them maximum flexibility and encourage them to think out of the box. Indeed, those investments led to a lot of other spin-off benefits in terms of our economy with satellite technology and Internet

companies and so forth. I think there are some long-term benefits that go well beyond this.

It strikes me that it is exactly the right time to recognize that this war on cancer is not working at least the way we hoped it would. It requires a fresh approach. It is a little bit like your personal computer when it has slowed down and not working so well. You have to reboot it. You turn it off and turn it back on for kind of a fresh start, and that is what I think we need here, and a new approach that really is enabled by technology, free of bureaucracy, fueled by entrepreneurship, and really facilitated by collaboration.

There are lots of great initiatives that are in place. Some of the testimony you will hear this morning talks about them. I would just urge you to focus on this strategic framework, less on these particular issues, and more on the broader context. Think of it more as an opportunity to build a platform for innovation.

Particularly, whatever you end up ultimately deciding in terms of how much of the national resources should be put against this effort, make sure a significant portion is really set aside for strategic initiatives not focused on any one of these specific issues, but these broader issues such as what is happening with the cancer genome atlas or the bioinformatics networks, sort of an Internet for cancer research, or a biomarker database—broad efforts that really apply to all cancer.

Then over time, I think it can apply more broadly to healthcare as well because the other thing I have noticed, as I have learned more about this, is even though we call it a healthcare system, it really isn't a system at all. It is sort of a kind of confused—and it really isn't even that much about health. It is more about disease care. We need an ethic, as several of you talked about, that really focuses on keeping people healthy and prevention and wellness, earlier detection of things so you can catch these things earlier when people do have these difficult life-threatening diseases, obviously with cancer being the centerpiece of that.

Just being able to deal with that in a much more thoughtful, much more personalized way and recognize that it is less about where the cancer starts and more about a systems approach even to the human body and approaching it in that kind of context.

I applaud the effort to really kind of reboot our efforts on cancer, restart those efforts, and bring a much more strategic approach. I would urge you to resist the efforts from our organization, ABC2.org, and many others to focus resources specifically on specific diseases. Obviously, we care about that. What seems to be missing after 37 years is this broader strategic framework and far more of those dollars need to—if there are any earmarks, it really should be for the strategic initiatives that can benefit all cancers and over time benefit our healthcare system more generally as opposed to the parochial interest of any particular organization.

Thank you.

[The prepared statement of Mr. Case follows:]

PREPARED STATEMENT OF STEVE CASE

Thank you, Chairman Kennedy for this opportunity to share my thoughts with this subcommittee, and for your commitment to this important issue.

My name is Steve Case. I co-founded America Online and spent two decades helping to make the Internet part of everyday life. Now I am the Chairman of Revolu-

tion, a company I started to give consumers more choice, control and convenience in important aspects of their lives. We are particularly focused on health care, and recently launched a new company called Revolution Health. In addition, I serve as the Chairman of Accelerate Brain Cancer Cure, ABC^2, an organization I founded with my late brother Dan to drive collaboration and innovation in the field of brain cancer.

ABC^2 was formed with the belief that the entrepreneurial model that has enabled so many technological innovations offers the best hope to increase the number of potential therapies discovered and move them rapidly into the clinic for patients. ABC^2 takes an innovative, results-oriented approach to giving researchers the active support they need to make critical breakthroughs, and helps fund outstanding and novel translational research aimed at discovering new treatments to end the pain and suffering from brain cancer.

ABC^2 continues to play an active role not only in research, but also in advocacy. This past Sunday, as a kick off to Brain Tumor Action Week, I joined more than 7,000 patients, survivors, and family members who gathered on Pennsylvania Avenue to raise funds for research and increase awareness. I was inspired by the lasting commitment of those who have lost loved ones to brain cancer and also by the more than 200 survivors who kicked off the race.

From 1950 to 2001, the death rate from heart disease fell 60 percent, but during that same period of time, the death rate for cancer has not changed. I think it is clear to all of us that the 37-year-old war on cancer has not had the impact that was envisioned.

My brother Dan was afflicted with glioblastoma multiforme (GBM), the most common form of brain cancer. Unfortunately, the prognosis for someone with a GBM is grim, with less than 50 percent of patients surviving more than a year following their diagnosis.

However, I am encouraged by new research emerging, much of which is being developed through collaborations between top brain cancer institutions, biotechnology companies, the National Cancer Institute (NCI) and the FDA. For example, a new therapeutic option was presented recently—bevacuzumab—that appears to effectively cut off the blood supply to brain tumors and shrink them dramatically. While this treatment will not cure brain cancer, it appears to delay the disease, improve quality and quantity of life, and bide time for the next breakthrough.

Bevacuzumab serves as a positive example of what we can accomplish when researchers, investors, and patients work together under an entrepreneurial model. The lessons learned from the development of this treatment should be applied broadly and should signal the need for a new strategic approach to cancer research and treatment.

Indeed, I am not here today to argue for more money for brain cancer research. Rather, I am here to share my views on cancer more generally—and suggest how we might be able to apply some of the lessons learned from building the Internet to fighting cancer.

All too often, the battle for research money ends up pitting cancer groups against each other, in what they perceive to be a zero sum game—some will win, and others will lose. The fact of the matter is we are all in this together, and all of us will benefit from a more strategic, networked, technology-driven approach to cancer research.

There was a time when information services operated autonomously—but it was only when they were brought together by the Internet that we made real strides. Similarly, our focus in cancer must shift to a more integrated approach—recognizing that even the way we label cancers may very well turn out to be misguided, as we learn more about pathways and invent new more personalized, more targeted ways to treat patients.

Should we invest more in cancer research? Yes, absolutely, for the reasons you'll hear today from my distinguished colleagues. The big breakthroughs aren't likely to come just from spending more money—they will come from changing how we spend money.

As is too often the case in business, ineffective approaches may be perpetuated simply because it was the way it was done before. While such an approach represents a comfortable path for many in large organizations, it also inevitably discourages innovation and institutionalizes inefficiencies. Since the mid-19th century we have classified cancer based on where it appears in the body rather than based on its molecular composition. This system has resulted in the creation of silos around cancer research, where scientists typically focus only on one type of cancer and rarely collaborate. In addition, it has created a climate where cancer advocates are all too often pitted against each other for limited research dollars.

We need to come together as one community committed to tackling cancer—and move away from the model that treats cancer based on where it appears in the body and toward a model where we focus on signaling pathways, new technologies, biomarkers and novel clinical trials.

The National Cancer Institute has already made significant strides in this direction with the creation of the Cancer Genome Atlas—an attempt to discover the genetic underpinnings of cancer. By understanding cancer based on its genetic underpinnings, we are discovering that what we thought was one disease—breast or lung cancer—are actually several unique ailments. The Cancer Genome Atlas is currently analyzing brain, lung, and ovarian cancers, but should expand this vital work to all types of cancer. This will be a powerful tool which will better enable us to classify different types of cancers and improve treatment of the disease.

A key component of this new approach will be to increase funding of biomarker research. Biomarker research will redefine how diseases are classified—not simply looking at their symptoms, but at their biologic underpinnings. What were thought to be single diseases are being split into separate ailments. If we better understand the pathways for different types of cancer, we will be able to target treatments more effectively.

As part of this strategic approach, we need to eliminate the restrictions that prevent NCI from pursing the most effective collaborative models. Congress is well-intentioned but—in my view—somewhat misguided in earmarking large portions of the NCI budget to specific cancers, which deprives the NCI from being able to adopt a more strategic approach. Similarly, while there is always the risk of abuse, the policies now in place limit collaboration and slow innovation by making it difficult for the NCI to partner with for-profit companies. We didn't preclude NASA from working with for-profit companies when we wanted to reach the moon, similarly, we should not prevent NCI from pursuing the most effective model to find a cure for cancer.

We also need to think differently about managing risk. We are so good in this country about reporting when something wrong happens, but too often fail to highlight our progress. When it comes to cancer we need post-approval surveillance of therapeutics to report the positive outcomes, not just the side effects. We need to learn from each encounter cancer patients have with their doctors and act on that information. The technology is in place to allow us to share this information in order to improve treatment. If retailers can analyze data at each of their cash registers, there is no reason why America can't do the same with its cancer doctors.

Although there is much work still to be done to fight cancer there is reason to be hopeful. Some breakthrough collaborative projects are in place, and the initial results are encouraging. For example, I already mentioned the Cancer Genome Atlas, exactly the kind of networked strategic approach we need more of. Another project that could result in real breakthroughs is the National Cancer Institute Nanotechnology Initiative. These represent good first cross-disciplinary steps, but a much larger commitment to these sorts of strategic, collaborative initiatives is needed.

As we focus on systems and technology and collaboration, as we must, let's not forget that this is all about people—about patients, and their families. Our health care system has been organized around the payers for the past half century—not around consumers. We need to put consumers—patients—back at the center of our health care system. For example, cancer patients need to be more empowered with information, and have the opportunity to take an even more active role in managing their care. This was one of the lessons I learned on a personal level, when my brother was battling his cancer.

My brother passed away, but the work of the organization he started lives on. I am proud of the strides we have made in driving collaboration and innovation in cancer research. As I spent more time learning about the health care system, I concluded that more needed to be done—and that I needed to put my money where my mouth was. That led me to start a new company, Revolution Health. We are just getting started, and we recognize there is a long journey ahead, but we are hopeful that we can play a small role in improving our Nation's health care system. Our focus is on getting consumers more actively involved in thinking about and managing their health and the health of their loved ones, so they can live healthier, happier, and longer lives. Our efforts to really engage consumers, along with the creative efforts of many, many organizations, will hopefully set us on a path towards a health care system driven by consumers, shaped by market forces, and powered by technology.

I would like to thank the committee for giving me the opportunity to join you today to share both my personal and professional experiences—and passion—around revolutionizing health care, and fighting cancer. I applaud your commitment and

stand ready to assist you and the cancer research community to hasten the search for cures.

The CHAIRMAN. Thank you all. Enormously interesting, valuable testimony. All very different and all on target.

I think most of us understand that we are living in the life science century. I mean, the opportunities that are out there in terms of these breakthroughs are virtually unlimited, with the mapping of the human genome. Senator Harkin, again, was so involved and engaged in that.

The opportunity from metabolical and health and research are really unlimited. I think we also have a sense of we can't legislate, as all of you have pointed out, that you are going to have a cure for cancer. We understand that. We also understand the American people have an interest. This affects so many families.

If Government is about anything, it is also about trying to reflect what people's concerns are, and they are concerned about this disease, and they want some additional focus and attention. They want to try and bring the best of not only the research, but I think, as all of you have outlined, the newer kind of approach that is going to marshal all of the elements that this cancer brings and to do it in an innovative and creative way.

That seems to me what we are hearing from all of you, and certainly what we have heard about before. I am interested in your own thinking about the areas that are of greatest concern to you—I, for one, am a parent of two children who had had rather devastating lung cancer, which is a killer, and another the osteosarcoma, the cancer of the leg bone, which was dangerous—the good fortune of having early diagnosis, getting ahead of the curve.

I mean, I am absolutely convinced that that made all the difference just in the early kind of treatment and how we are going to be able to do that for people. As Elizabeth Edwards talks about the early kind, making sure, and others have talked about access. If you are not going to get the access, you are sure not going to get that early diagnosis.

What is your own experience regarding the importance of that early diagnosis, of trying to find out? Maybe you can talk a little bit about those preventive aspects of it, and then a dash about these breakthroughs that we are having now in terms of being able to get early detection.

It seems to me if we get this early kind of detection, early kind of assessment of this and continue to bring the focus and attention to this, continue to do these clinical trials, but have these early kinds of detection and prevention aspects of it, we can really make a very large and substantial difference within the broader context.

Elizabeth, do you want to talk a little bit about this?

Mrs. EDWARDS. Well, what we have to do is remove the impediments to early diagnosis, to early screenings. There are, of course, way too many of those. The largest impediment is insurance. The percentage of women who are diagnosed with Stage 3 or Stage 4 cancers, which means they have metastasized to some other part of your body, and that decreases your chances of survival, is 2.5 times larger for women who are uninsured than it is for people who have insurance.

Those statistics are repeated in each kind of the cancers that people at this table represent and the other kinds of cancers not represented there. Your chances of survival are so much greater before metastasis. Lung cancer that has metastasis, you have a 3 percent chance of survival. Colon cancer before metastasis, 90 percent chance of survival. After metastasis, 10 percent chance of survival.

Not to mention, and something that is important, as Lance was pointing out, the effect—the economic effect. The treatments are less debilitating, less expensive, less disruptive if the diagnosis is early. We need to make certain that people have access. Sometimes it is demographic in terms of whether or not they have the finances to pay for insurance or whether they have an employer who pays for it. That is something you can solve.

Another one of the reasons, geographic, we see it in North Carolina, I know, because we have a large rural area. I am certain Senator Murkowski sees it in Alaska as well. In rural communities, it is much harder to get the kind of effective screenings. We have better and better—I will use my own disease—mammograms, for example, but they are not available unless you drive lots of hours to get to them.

Some of the kinds of investments that we make, they may seem expensive on the front end. The truth of the matter is that every dollar we spend on the front end saves us $5 on the back end at a minimum, and probably more as time goes on and increases the quality of the life of the people who are going to suffer from this disease until we find out what it is that causes it.

I am convinced we are going to find the answers to these, but not without the investment. And I want to applaud what Steve Case said, the investment that looks beyond what we normally—the protocols that we are normally following right now.

I also want to comment on something that Susan G. Komen is doing, and that is they have invested like $600 million in basically allowing people to do just what Steve was talking about, and that is give the wild ideas a chance, basically. The way that we fund research right now doesn't allow that to happen. But you are precisely right. We need the early detection that saves us money, allows us to make the investment in some of these other things.

I have to ask the indulgence of the committee in order to be feted later. If you do not mind my leaving?

The CHAIRMAN. No. No, no. We are very grateful for you arranging your program and enormously appreciative of your presence and the eloquence of your comments on this. We will excuse you and give our very best to the Senator.

Mrs. EDWARDS. Thank you, Senator Kennedy.

The CHAIRMAN. We will follow the 6-minute rule here. My time will be up, and I will recognize Senator Murkowski.

Senator MURKOWSKI. Well, thank you, Mr. Chairman.

Mrs. Edwards, as you leave, I want to again acknowledge all that you do and your efforts to remove these impediments, and they are very, very real. We look forward to working with you on that.

We have in the State of Alaska some geographic issues that we deal with when we talk about the impediments to access, and our geography is simply never going to change. And in my lifetime, we

are probably not going to have any more significant roads added to our road system than we currently have.

About 30 years ago-plus, my mother was involved in an effort to provide for a mobile mammography unit and recognizing that you are pretty limited if you are just sticking to the road system. For the past 30 years, every summer, they put a mobile mammography unit on a barge. It goes up and down the river system, stopping in the little villages where you might have only 80 people. We are providing for a level of screening that we are bringing to them.

In the communities that are not accessible by river and not accessible by road, every now and again, we can get the Air Guard to do a mission and to fly one of their aircraft out there. We put the mobile mammography unit in, and what we are seeing in terms of removing that impediment to access is that the screening rates among the Alaska Native women are greatly increasing. And as we are able to screen, we are better able to diagnose earlier.

I look at that as an example of how in a big State with real impediments to access, we are reaching women, but we need to be doing more things like this in rural America. We need to be going to the people. We have got to be more creative.

Mr. Case, I so appreciate your testimony about the collaboration and how we change the way we view the disease and the approach to the disease and the research that goes with it. I was at Johns Hopkins a couple of years ago, touring through the facility there, talking to the doctors and talking to the researchers. I had an opportunity to look specifically at what was going on with ALS.

You want to talk about silos, we are pretty siloed in this system. Over there, your grant depends entirely on what you are able to produce in your research. And if you share it with anybody else, then your future grant opportunity is potentially jeopardized.

I may have information that perhaps hasn't allowed me to break through, but if I were to share it with another researcher who is working on Parkinson's or another disease, we do not allow for a level of collaboration that can promote, I think, the kinds of breakthroughs that we are all hoping and praying for.

We have got to do more in terms of breaking through these impediments that we have put in front of us. A question on that, and how we can enter into more of these public/private partnerships and the need for NCI to do that. Do you have any great ideas as to what we can do now to further enhance that type of a public-partnership approach?

Mr. CASE. It is obviously complicated, and I am still learning about it. It seems to me that we have focused too much on different silos, as we have discussed, and really defining the problem incorrectly. We are drilling for oil in a particular hole and telling people exactly where they are supposed to drill and exactly how they are supposed to drill. Maybe we should be drilling somewhere else, or maybe we should figure out another way to drill, or maybe we shouldn't be drilling at all and should be focusing on alternate energy. Using that as an analogy.

I think we forced the system over the past few decades into these little, focused silos and then put all kinds of restrictions, understandably, given a fear of abuse or trying to correct for abuse. A lot of restrictions that basically impede innovation and impede

progress and impede collaboration. I think it does require a clean-slate approach. That is why I used the analogy of DARPA and NASA.

When there really was a need to do something and do something quickly, the tendency was to put the resources there and provide a fair degree of flexibility and let people do things that are a little bit out of the box. Right now, we have moved it too much towards being risk averse, and as a result, we are not seeing the level of innovation that we thought.

Some of this goes back to how you define the problem. To the extent that you are looking at it, say, from a context of brain cancer or ALS specifically, you are missing the broader dynamic in terms of what is really happening with the brain. And similarly, you need a more systems-based approach to health in general.

Going back to early detection, we do some things on the philanthropic side, such as ABC [2] and the Case Foundation, also do some things on the for-profit side, funding interesting companies that are doing entrepreneurial things. The one company we provided some seed funding to is a company called BrainScope. It is still in development.

The reason I was interested in that was they initially were focused on this little device—it is almost like an iPod—to basically diagnose concussions on the field. They are working with the NFL on something like that. We also thought there may be an opportunity over time to use it to detect other things, including, maybe even over time, brain tumors.

Using the same device that is right now focused on concussions could be used in terms of traumatic brain injury on the battlefield, but could be used for brain tumors? Nobody, looking at this from a brain tumor context, would ever have come up with this idea, but defining the problem differently and having an entrepreneurial, technology-driven approach to it may end up providing some leverage not just in the area it was targeted, but more broadly.

I think it really is kind of taking a step back, and that is why I do, as I have said several times, applaud this legislation, applaud the effort just to take a fresh approach. Nobody knows exactly how it is going to turn out. What we do know is that what we have tried over the last 37 years hasn't gotten to where we want to go, and it is time to try a new approach.

It is going to require more flexibility. It is going to require more collaboration. And it is going to require more innovation, which is going to be hard because, basically, we are going to have to trust people to do the right things in the right ways and give them the tools to really think out of the box.

Senator MURKOWSKI. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Senator Harkin.

Senator HARKIN. Again, thank you both very much. Thank you, Mr. Chairman, for your great leadership in this area.

I just want to focus on a couple of things. First, the early screening and detection. We do the research, and as you said, Mr. Case, we have got to think anew about how we do that research and fund it, and proceed on that. We also have to focus on the immediate

problems of not only access, but early screening, detection, treatment, survivorship.

Last year, Lance, you were here when we introduced that bill in May 2007, the Cancer Screening, Treatment, and Survivorship Act, for that very purpose. It was sent to the Finance Committee, and I haven't seen it since. I was hoping we might get sequential or referral or joint referral to this committee, too, because it has Medicaid in it. As you pointed out, if we can get to people early, their survival rate is tremendous. If you don't, then it is very low.

What we have done—just since we did that—we now have five centers, as you know, in the United States for colorectal screening. And those have really helped in terms of survivorship, finding early detection for polyps, and just in the last couple of years has done a great job. But there are only five centers.

Here it is. Since 2005, we screened 2,300 uninsured men and women ages 52 to 64, 272 polyps were identified and removed, 70 individuals that have been diagnosed with colorectal cancer are now in treatment. That is just out of 2,300, over 10 percent. Just think how many more people are running around out there if they had early detection of colorectal screening would be saved. We know they can do that.

The same is true also of breast cancer screening. In 1990, I funded the first money for early detection program for breast and cervical cancer. We started with $30 million a year. It is now up to $200 million a year. Since that time, 3.1 million women have been provided more than 7.5 million screening examinations, diagnosed 33,000 breast cancers, 2,000 invasive cervical cancers, and 1,006 pre-cancerous cervical lesions.

All of this early detection, but still, we are still only able to reach 20 percent of the eligible women in this country. And again, it seems to me that we have to focus on early detection and early screening. I know that was some of your points that you were making on that.

I had five siblings, and four of my siblings died of cancer. The two that I focused the most on are the breast cancers. My two sisters died at an early age of breast cancer. Why? They didn't have early screening. They were fairly low income. They lived in rural areas or places where they didn't have early screening, and by the time it was detected, it was way too late. If it had been detected earlier, it would have been a different story.

Somehow, we have got to get more of our funding and more focus on that early detection, treatment, and survivorship that you talked about. I don't know that I have a real potent question for you other than just any other thoughts you have on that and what we should be doing? We use, of course, the Centers for Disease Control and Prevention to get out there. They know how to do these things. Again, they have a lot on their plate, too. Developing vaccines and fighting flu epidemics and threats of terrorism, that type of thing.

Still, CDC and our public health infrastructure, they have—the structure is there to do it. We haven't funded it. We haven't built it up, but we just need, I think, to focus more on it. I just wondered if you had any more thoughts on that, on the early detection, treatment, and survivorship aspects of this?

Mr. ARMSTRONG. Well, first of all, thank you for all of your help. You have been such an ally of ours, and we appreciate it.

Secondly, I feel a little as if I am not qualified to talk about screening and early detection because I simply was probably the exact opposite of that. I was a young, hard-headed athlete that, as I said earlier, thought he was invincible. I am not sure that I could have waited any longer. It is a little ironic that I get to speak to that.

It is a fact. And again, sitting on the President's Cancer Panel, spending the better part of a decade dealing with this, we know that that works. If you just simply look at colorectal cancer and what we discussed on the last piece of legislation you were talking about, 56,000 deaths a year to this disease, which is a big number in terms of this whole problem. If every one of those 56,000 people were screened properly, we would probably save 99 percent of those people.

Yet, you will hear that screening is expensive or early detection is potentially expensive. Ultimately, people will be diagnosed, and they will be treated, and treatment could last a long time. As Elizabeth said, it could become very expensive. While we save a dime, ultimately, we are going to end up spending a dollar. Economically, it doesn't make any sense.

Morally and ethnically, obviously, it doesn't make sense because when you are losing 56,000 Americans a year to that particular disease, that is too many.

The other thing I will say—and Steve touched on this, too—is the imaging aspect of this. If you go back to look—I mean, I don't know. I wasn't around in the 1800s, but when they thought you had a problem, they looked at you, and they said, "I think you have a problem."

Then it came along, and imaging improved, and the technology behind that improved. We have the X-ray and we have the CT scan, and then we have the MRI, and now you have methods to really detect any disease and a lot of diseases. And that even goes further towards blood tests or tumor markers in the blood, things like that, where you can really monitor disease and monitor progress, No. 1.

For myself, if I ever felt like I was getting sick again, I wouldn't go get an MRI or a CAT scan. I would walk to the doctor's office and take a simple blood test and have my tumor marker checked, and I would know. My gauge is there. Most people don't have that opportunity. So the patient is confused. The doctor is confused because they can't monitor the work that they are doing. That all will develop over time.

All of that stuff, again, we have to encourage and we have to fund and we have to implement across the population, not just the proper communities or the haves, but also, unfortunately, to the people that some refer to as the have-nots.

Again, it is a simple solution to a complicated problem. We know these things. If you go back to the continuum and you talk about prevention, in any community, we know what works—reduce tobacco, sun, better diet, and exercise. We know those work. Let us fix that problem.

If you go to screening and early detection, we know that that works. We know that, morally, it makes sense. Economically, it makes sense. Let us do that.

The access issue is, I know, more complicated and on the Federal level, but needs to be researched and ultimately needs to be solved. A key word that I think we have been using in the last 5 minutes is collaboration. Collaboration will work on a lot of these levels, and somehow we have to find a way to solve that access piece through collaboration, and then on and on and on. We have some answers to the easy questions. We are just not doing it.

I think, ultimately, the last thing I will say to this is the reason that I think we are not doing this is because this is a complacent disease. This disease and its constituents in our society has grown complacent to this disease. People are used to cancer. People are used to losing—and while it is sad, and everybody is upset in the family and in the community, we have grown used to losing people to this disease.

If the bird flu comes along and five people die and we give $7 billion, people think, "Oh, my God. We are all going to get the bird flu." Or any other kind of ailment or illness or plague that comes along. This disease is an old problem, and we have lost our focus on the problem, I think. As I said earlier, I think it is going to require a renewed fight, a renewed vision, and Steve talked about that.

We might need to overhaul some things, and people don't like to hear that the system is broken. Don't tell them that I said the system might be broken. Some things have to change.

Senator HARKIN. Thank you. I appreciate that very much. Thanks.

Mr. ARMSTRONG. We will see you at——

Senator HARKIN. I will do the first couple of hours. Then I will wave good-bye.

[Laughter.]

The CHAIRMAN. Senator Burr.

Senator BURR. Thank you, Mr. Chairman. Again, thank you to both of you for your willingness to be here.

Lance, let me go right to something you have repeated over and over again. The system does not pay for maintaining wellness or preventing illness. It focuses on paying for sick care.

Listen, I am not sure that there is any way you can summarize how the system is broken better than that right there, and I think the fundamental problem in our healthcare structure in this country today is that we have a system that is designed to trigger when people get sick. It is not designed to try to prevent illness or to encourage healthy decisions.

It is pretty tough to say that you can go in and you can change the architecture, Steve, as you said, and just fix the things that are broken without the overall architecture being redesigned in a way. Steve, you brought up several times DARPA, and I am not sure that everybody here knows what DARPA is.

I am amazed how few people understand how unique the DARPA model is, but more importantly, how it reassesses risk. Let me ask you, could you take the DARPA model, and bring that fully into healthcare and make it work, in your estimation?

Mr. CASE. I think to a large extent. It depends on how you define it. The way I think of DARPA was at a time of national crisis, really, around security issues, particularly in the middle of the past century, the sense was that we really needed to have a focused effort that gave people working on that the resources necessary and the flexibility to make decisions and to do whatever it took to be successful on that mission. I think that approach is certainly applicable.

Now, that approach did lead to some seed investments, including in some different companies, and over time led to the creation of the Internet. That, then, had significant economic benefits and, I think, quite a number of other benefits. The Internet wouldn't exist today if there wasn't a concern raised 50 years ago around security that led to the creation of DARPA and the DARPANET, which became the Internet, which now has become a part of everyday life.

It really required this kind of SWAT team effort in saying here is the mission. Here are the resources to accomplish the mission, and we are not going to tell you what you can't do. We are going to tell you what you need to accomplish. That kind of effort is hard to do these days. I recognize that.

Senator BURR. As you know, with the DARPA model, had they determined 2 years into the research, you can't do it, it can't be accomplished, DARPA had the ability to cut the funding off right there and to redirect those efforts into another breakthrough area. Are we ready for that in health research?

Are we ready for somebody to head down that trail, thinking that they have identified that marker, as Lance referenced, only to find out it is a dead end? To be able to redirect the money, do you think there are people within the health community and the patient, the consumer community, as you put it, who are ready for us to take that type of approach?

Mr. CASE. Well, my view is many of the people in the community that I have talked to—and again, I am no expert in this—recognize the system is broken, and have their own particular formula in terms of how to fix it. There is always going to be some institutional resistance to major change. That is always going to be the case. People are always going to tend to cling to the status quo because that is sort of their comfort zone.

Broadly, it is recognized that some major change is needed, some disruptive approach is needed. We need to bring more of an out-of-the-box approach. I think it really becomes an issue of political will, more than anything else. That is why I support this legislation and applaud your efforts to try to put something forward that is a little bit more out of the box and does put some pressure on the system.

There are a lot of good ideas. I read some of the materials on the next panel, a lot of good prescriptions from FasterCures and others, about approaches that might make sense going forward. The ideas are out there. The question is how do we take those great ideas and embrace them and champion them and fund them and not be overly prescriptive in terms of how you implement some of those programs? That is where we tend to get into trouble.

We have too much of a culture now around health, as I said earlier, that is risk averse. Worried about what might go wrong. The focus needs to be on what might instead go right.

Senator BURR. Well, there is no bigger advocate up here than Senator Kennedy for health IT. Yet we still can't seem to get a bill produced because individuals are concerned with privacy issues that could easily be addressed through de-identifying the data. Yet by pooling the data together we can glean areas that show great promise for us to produce research in.

I remember years ago when Trent Lott helped me—and I think others on this committee—create an Institute of Biomedical Imaging at the National Institutes of Health, and the National Institutes of Health didn't want it at the time. We weren't putting the money into the potential breakthroughs on the imaging side so we could make earlier detections. Yet now we are in a State where we look and say one of the most crucial things is that we get people in and detect problems at the earliest possible point because we know our chances of survival are greater the earlier we detect a cancer.

I think we have pushed the envelope against the system. Let me assure all of you that it will take a continued persistence on the part of you and on the part of Congress because we will go into areas where people are very uncomfortable with the change, whether that is in the peer review process that we have currently at NIH, or whether, Lance, it is in restructuring a healthcare system that actually creates an incentive for individuals to make healthy decisions versus a system that is only triggered when you get sick.

I, for one, am willing to tackle it, and I look forward to continuing our conversations with both of you.

I thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. Case has to leave shortly. We have three Senators here that haven't had a chance. Do you think—could I ask each of them to take a couple of minutes or maybe——

Mr. CASE. I am happy to stay. This is more important than my other commitment.

The CHAIRMAN. Well, thank you. Maybe they will each have a question for you, and then I know, as I mentioned, you will sort of have to go along. So we will do Senator Dodd, Senator Murray, Senator Brown.

Senator DODD. Mr. Chairman, I will be brief. I was late getting here this morning, and I apologize for getting here late. Thank you both, and thank Elizabeth Edwards as well. Thank you, Mr. Chairman. Once again, you have been at the forefront of this for your entire career here.

Can you hear me all right? Let me just quickly—a couple of quick questions for you. One is we have been trying for a long time to get the legislation to regulate, have the FDA regulate the use of tobacco. Talking about these issues here, I can't resist asking the question since you are here and can give us your thoughts on that.

We are talking about managing cancer, but obviously, until we are able to regulate one of the major causes of cancer, we have a problem. I would like you to address that issue, if you would.

And second, a related issue is palliative care and also pain management issues. I am working with Senator Hatch on a pain management issue right now, and I know it is a major issue. You have, Mr. Armstrong, dealt with this one way. Different people deal with it different ways. It seems to me a major question as well, and I wonder if you might just address those three issues.

Mr. ARMSTRONG. Well, the first being tobacco?

Senator DODD. Yes.

Mr. ARMSTRONG. Of the years that I spent on the President's Cancer Panel, if you asked me to sum it up in one word, what would be the one thing that you just kept hearing over and over and over those years and years and years, tobacco use and abuse would be the No. 1 thing. I mean, across the field, which unfortunately translates most of the time into a lung cancer situation, whereas basically an orphan disease is tremendously underfunded and underserved.

Tobacco is what it is. It is an addictive drug that is marketed and targeted to the youth of America. If you consider that the budget of the National Cancer Institute is $6 billion, big tobacco in the United States alone, just to market that drug, $15 billion a year in marketing, most of it directed to our children.

As a father of three and as a cancer survivor, that is troubling. Listen, certainly people have the right to make their own decisions and choose unhealthy habits if they want. But, something isn't right with those numbers. I think that has to change. I am not a Senator or a policymaker. I don't know the solution.

The science will show that tobacco is, No. 1, obviously awfully addictive. And No. 2, more times than not, is awfully deadly. I think as a society that we have to address that in some way.

The second question was about?

Senator DODD. Was palliative care and pain management issues.

Mr. ARMSTRONG. Yes, as I said, I don't know—in the beginning, I talked about the continuum of this disease, and it starts all the way from prevention all the way to end of life. Palliative care is something that has to be addressed. It is the sixth area in the continuum, in my opinion.

If people continue to slip through the cracks of this continuum and ultimately are not going to survive, they deserve to die in peace and surrounded by friends and family and with a whole heck of a lot of pride and know that they tried everything that they could to live and that they are ready to pass on. That is part of it.

Certainly, they don't deserve to die in pain or in a sterile hospital room or wherever that might be. They deserve the best, the best passing that they can. It is a very, you know—listen if you consider that we are talking about an idea, but in reality, you are talking about 560,000 Americans. I have sat up here for 1 hour and 20 minutes. Since I have sat here, 80 people have faced that situation, 80. Today, there is going to be 1,500 of them that face that situation.

It is a real concern, and it is something that we have to acknowledge. Ultimately, it is something that we want to erase or we want to at least reverse.

Senator DODD. Steve, do you have any quick comments on that at all, on the tobacco, FDA regulation of it?

Mr. CASE. Not really, other than sharing your view and Lance's view that it is obviously a problem. It has been known for decades it is a key cause of disease and a key cost to the healthcare system. So just continuing on kind of "business as usual" just clearly does not make sense.

That is an instance where we know there is a problem. We know what the solution is. We just need to be bold in taking action. I know there are a number of employers that are actually looking at ways they can modify even their insurance programs to try to have a carrot-and-stick kind of approach. Everybody has to do whatever they can do to try to encourage healthy behaviors. There is obviously nothing more obvious than trying to prevent people from smoking.

Mr. ARMSTRONG. Can I just add one thing to that? That is something that I have been very passionate about and just selfishly because I don't like to walk into a restaurant or a store and sit next to somebody that is smoking. I raced for 15 years in Europe, and I was around enough cigarette smoke to last me a lifetime.

I think local communities or States that are smoke free is the way to go. It is really an issue of public health and really an issue of fairness. When you walk into a restaurant, I mean, why would one person be allowed to exercise their own freedom and jeopardize the health and wellness of 10 others? That is an issue of fairness.

That should not be—if it is a single mother of three that is waiting tables at a bar or restaurant, and she has got to be around that? That is not fair. If you want to smoke, fine. Step outside and have your cigarette and come back in.

I think when you talk about tobacco, obviously, there is the issue itself. There are the side effects and the secondary effects that that particular drug or that particular habit imposes and inflicts on other people. I have asked long and hard and asked all of the presidential candidates whether or not America should be smoke free, and I think that the consensus is that it is better left to the cities and the States.

As you see, now you have a city like New York City or Austin, TX, or Los Angeles, or States like Iowa or States like Wisconsin——

Senator DODD. And in Europe. Europe is doing——

Mr. ARMSTRONG. I was going to say, now you have a country like Ireland, a country like—I mean, for God's sake, Paris, France, is smoke free now.

[Laughter.]

Senator DODD. Is it 3,000 young people a day, I think, that start smoking? I think is that number right?

Mr. ARMSTRONG. I don't know the number, but that is a startling number. I can tell you that I asked—on one of the panels, I asked one of the experts at what point are you addicted? They reckoned that after about 100 cigarettes, you are addicted.

So, you do the math, and you have spent—I don't know what cigarettes cost. I haven't bought any ever. You have spent $10 or $20 or $30, and you are hooked forever. It is one of the hardest

drugs to kick. We have to address this, especially with our kids. If we are marketing to the kids of America, that is not right.

Mr. CASE. It also ties in obviously with the healthcare system issues generally. It is unbelievable that we spent $2 trillion in healthcare, one sixth of the economy, keeps going up. You look at the underlying cause and that is clearly a contributor.

It is bad enough that the secondhand smoke is annoying you in a restaurant, in fact, it is worse that you are actually indirectly subsidizing other people's unhealthy decisions.

The CHAIRMAN. Senator Murray.

Senator DODD. Thank you.

Senator MURRAY. Thank you very much, Mr. Chairman. Thank you to both of you for coming and for your passion on this issue.

I come from the State of Washington, and cancer research is something that is very important in my home State. Fred Hutchinson Cancer Research Center in Seattle doing great developments on everything from transplantation, targeted cell treatment, gene therapy. We have the Seattle Cancer Care Alliance, which is doing some fascinating research on proton beam therapy. This is something I think all of us really care about, and we are excited about a lot of the opportunities.

We heard a lot about prevention, absolutely agree. New research to find new cures. The one issue that doesn't get a lot of attention, which I would like to ask you about, is survivors. It is great. We have cancer survivors, but are we doing enough to address the issues that they face, whether it is psychological, whether it is getting back into the workplace and being accepted, quality of life, secondary cancers?

What should we be looking at in terms of that population that we are not focused on today?

Mr. ARMSTRONG. Well, I think we, at the Lance Armstrong Foundation, have made—that has been the bulk of our priority the last 5 or 6 years. I had the good fortune of being with Ellen Stovall last night for the National Coalition of Cancer Survivorship benefit. She is really the pioneer in this field.

In the last decade, we have done a lot. I think, initially, cancer was a death sentence, and so nobody worried about if you live. If you lived, just be glad you lived. It is not like that anymore because the numbers are straightforward. There are 12 million of us in this society that are living with this disease.

There are a lot of things to consider, the economic issues, the personal, the emotional, the professional issues. Fertility is a big issue for both men and women. All of these things have to be addressed. As I said in my opening statement, to me, it boils down to quality of life. Regardless of whether or not you have had cancer or not, we all deserve a high quality of life.

All of these things have to be looked at, and certainly a cancer survivor deserves to have children. A cancer survivor deserves to continue on with their job and not be discriminated against in that aspect. They deserve to—you know what, if they want to go out and run a marathon, they deserve to do that. If they want to go out and get back on their bike for some crazy reason and win seven Tours, they deserve to do that.

All of that stuff, and some of it is scientific, has to be looked at as to how we preserve that quality of life. Let's face it, chemotherapy is chemotherapy. Ideally, in 10 or 20 or 30 years, you look at chemotherapy and you go, "Jesus Christ, did we really do that to people?" The fact of the matter is, is that the drugs are toxic, and there are inevitably side effects in and around those drugs.

The best example would be my situation. I started on standard treatment for testicular cancer. If I had continued on with standard treatment, I never would have gotten on my bike again. I switched doctors after one cycle. I ended up in Indianapolis, and my doctor, Dr. Larry Einhorn, who essentially cured the disease 30 years ago, he said, "Lance, do you think you ever want to race again?"

I thought, "Well, I would like to live. But, I guess if I get that part down, yes, maybe I will race again." He said, "Well, then we need to switch your treatment." The downside to that was that I had to be an in-patient and essentially stay in the hospital for the entire time.

That simple decision of him taking me off standard treatment and putting me on an alternative treatment that took away bleomycin, which is highly toxic to the lungs and would have prohibited me from ever doing an endurance sport, that decision, that day, that minute, preserved my career.

Now that is a scientific answer because we know now that bleomycin is toxic to the lungs and causes scarring, and I never would have—I would have had trouble getting up stairs. That is—selfishly for me, I am glad he did that. I am glad he asked that question, and I am glad I stayed in the hospital.

There are other issues that are equally, if not more important. Again, fertility is a huge, huge issue for both young men and young women or anybody that wants to have a child. Then the emotional stuff and the insurance issues and professional reasons. It all boils down to quality of life.

People who were used to a quality of life that they had before the disease, that should not change. In fact, you might argue that they should have a higher quality of life because they appreciate that life so much more.

Senator MURRAY. Thank you. Thank you very much, Mr. Chairman.

The CHAIRMAN. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman.

Mr. Armstrong, I want to ask you a couple of questions. Earlier this week, I was at the James Cancer Center in Columbus, OH, and met with a fellow named Merle Farnsworth, who is in his 60s, has cancer, is in the midst of a clinical trial, and had his insurance cut off when he enrolled in the clinical trial.

Our understanding is, some 20 percent of people in clinical trials, cancer clinical trials, have had serious problems with their insurance companies. They are not only fighting their disease, they are fighting their insurance company, and we know we want to change that.

Talk to me, if you would, what—the thousands of patients that have participated in clinical trials through the years, what are those trials, can you sort of tell me what those trials have meant to you and your healthcare?

Mr. ARMSTRONG. I know a lot—at least, I think—about clinical trials. I have spoken to them a lot. If my time in this fight has—the one thing that I have heard the most is the tobacco issue. The second most common thing that I have heard would be clinical trials.

Everybody in this field agrees that if we could enroll more people in clinical trials, we would have much greater success. The proof is actually in the pudding in that if you consider childhood cancers 20, 30 years ago had very low participation in clinical trials, and the death rate consequently was very high. That has completely changed. I think the latest number is 80 or 90 percent of our children—not children, our children—are enrolled in clinical trials, and the cure rate directly reflects that.

Meanwhile, in the adult population, I think the latest percentage is 3 to 5 percent of adults are in clinical trials, and of course, the death rate also reflects that. A very tricky situation. I don't know the answer.

Again, many of these things boil down to fairness. If somebody is willing, in my opinion—and let me just say that I was not on a clinical trial. I am the product of somebody that was on a clinical trial. I am grateful for the pioneers that came before me and said I will try that. I have got nothing to lose. I am going to die. Let us try it. And therefore gave life to tens of thousands of young men in this country.

That has to be respected. Scientifically, if you asked, if you put the 100 best researchers in the room and you said, "OK, what do we need to do," and they all agreed that we have to increase participation in clinical trials, and that has to be funded and that has to be provided to everybody, then my answer would be, well, we have to do that.

Of course, nobody wants to fight the disease and fight an insurance company. That is incredibly frustrating. The facts are there, and I would fall back on the facts.

Senator BROWN. You had said earlier that you had served two terms on the President's Cancer Panel, but that few of the recommendations made by the panel ever came to fruition. Talk about that. Why weren't they?

Mr. ARMSTRONG. Well, it was a very interesting time sitting on the President's Cancer Panel because it is called the President's Cancer Panel, and most of the people before I would go—and this is slightly off the subject, but I will answer the question. Before I would go, they would say, "When you are there, tell the President this is what I would like to see." I never saw the President at the President's Cancer Panel meeting, but that is not the point.

Other people that would come to testify would say, "Tell the President this." They really feel like the line between them and change is that direct. Again, I said earlier that I think that this issue has grown complacent. I am not foolish and I know that in our society we are conflicted as to how we allocate money, how we allocate resources, where we decide to fight. This is not a priority in our society to fight.

Regardless—and I will remind you that the role of the President's Cancer Panel is to oversee the actions of the National Cancer Institute. Whatever plans we put together or wanted to imple-

ment, the fact is that they have to be given proper priority and they have to be given proper funding, and we don't have that.

All great ideas, but if we don't have the funding because the funding is going elsewhere or priorities are elsewhere, then they won't be acted upon.

Senator BROWN. OK, thank you.

One last comment, Mr. Chairman. I was on the Health Subcommittee in the House of Representatives 15 years ago, when it was then-Chairman Waxman who, in those days, brought six or seven executives, CEOs from tobacco companies. The famous picture in the paper, they all raised their right hand and then were a little close to going over the edge on the truth talking about nicotine addiction.

The one thing that hit me during that hearing was that—as we talked about 400,000 people die a year from smoking—the tobacco companies, no matter what they said, have to find 400,000 new customers every year just to stay even. That is why they have had such focus over the years—in spite of Senator Kennedy's and others' efforts, to—on going after and marketing to children.

Then you take that further, and it is those same CEOs when I asked them some questions that they were willing to take down their billboards near schoolyards and doing certain things like that here, I asked them if they would be willing to do that around the world, and they just went down the line and said, "no." That is a whole other issue of what our tobacco companies have done internationally, but you know that.

The CHAIRMAN. Thank you.

I want to thank all of our panelists, Mrs. Edwards, Mr. Armstrong and Mr. Case. This has been enormously helpful and valuable. Really very constructive and very, very positive. A lot of good recommendations and suggestions, and we would like to follow up with you. We will follow up with you. We are grateful for you taking the time and joining with us. Thank you very much.

Our second panel—Mr. Edward Benz, who is president of Dana Farber Cancer Institute in Boston; Greg Simon, who is president of the FasterCures; and Hala Moddelmog, who is CEO of Susan G. Komen for the Cure.

Mr. Benz has been president of the Dana Farber Cancer Institute, Boston since 2000, active NIH-funded researcher, over 200 published articles, past president of the American Society of Hematology, the American Society of Clinical Investigation, and American Association of Cancer Institutes, currently an associate editor of the New England Journal of Medicine.

Gregory Simon is president of FasterCures, whose goal is to save lives by saving time in the discovery, development, and delivery of treatments and cures for serious diseases. He was domestic policy advisor for Vice President Gore 1993 to 1997, then went on to become CEO at Simon Strategies, a consulting firm in biotechnology, healthcare, and information technology.

And Hala Moddelmog, who is president and CEO of Susan G. Komen for the Cure, former Fortune 500 exec, and joined the Komen in 2006. Under her leadership, the foundation has implemented a new grant mechanism to improve the discovery and delivery of cures, now pledged to invest $2 billion in the coming decade

in strategically important research and community outreach programs.

Thank you all very much, and we will start with Dr. Benz.

STATEMENT OF EDWARD J. BENZ, JR., M.D., PRESIDENT, DANA FARBER CANCER INSTITUTE, BOSTON, MA

Dr. BENZ. Thank you very, very much, Senator Kennedy. If you will permit me a moment of local pride? Thank you for so much that you do for Boston and New England and healthcare in the entire country.

Thank you, Senator Murkowski, and to all of the Senators here for taking on this incredibly important issue and for your sustained support of biomedical research and better healthcare.

With your permission, I would like to speak to you from several perspectives today. First, as president of the Dana Farber Cancer Institute and director of the Dana Farber Harvard Cancer Center, I represent tens of thousands of our patients, our supporters, our staff who are absolutely dependent on and committed to what you are trying to accomplish with this what I hope will be the decisive battles in the war on cancer.

As president of the American Association of Cancer Institutes, I represent the directors of the 92 comprehensive cancer centers around the country, and we are pledging our support, help, and assistance in any way as you try to figure out the best way to lead this country forward to conquer and to control cancer.

I would like to speak to you today from two other contexts that matter as much or more to me. First, as a physician and as a scientist, I have spent my life trying to understand the inner workings of cells and how they affect disease, cause disease, and how they might be turned around so that they stop doing that. As a physician, I have had the joy of telling people with blood-forming cell cancers that they have been cured and the agony of telling people that they weren't going to make it.

But most importantly, I am here today as the son, the brother, and husband of cancer survivors. Like so many of you, I wake up every day wondering if that cancer is gone forever or if the other shoe is going to drop. We are all in this together, whether we work in the field, whether we are advocates, whether we are patients.

You know the numbers. There are 1.4 million people in this country, roughly, who will be diagnosed with cancer this year. Over 500,000 will die of those cancers.

The good news, as you and others who have testified today have pointed out, is that we have 12 million cancer survivors that, in contrast to the year when I entered medical school in 1968, when the chances of living with cancer for 5 years were around 30 percent, almost 0 percent for a child with leukemia, it is now almost 2 out of 3 patients can expect to live 5 very good years or longer of life with a cancer diagnosis, and over 80 percent of children can expect to be cured if they have childhood leukemia.

That is the good news. The other good news is that we in the field are incredibly excited that from a scientific point of view, from the point of view of the tools that are available in information technologies, in systems research, that we can make the decisive push to make cancer a disease that can be cured or at the very least can

be rendered to be a very controllable chronic disease compatible with long-term good quality of life.

I and my colleagues in medicine, in nursing, in pharmacy, in healthcare in general, are also very frustrated and very worried because we think at a time when science is giving us the opportunities to make the decisive difference that the trends in this country in both healthcare and research policy and financing are going to prevent us from taking advantage of those incredible opportunities.

The Human Genome Project, which was made possible by the doubling of the NIH budget, that very visionary thing that I know so many of you supported, was an initiative made for the study and cure of human cancers. There is no other set of diseases that depends as much on the information that we get from the Human Genome Project as the 400 diseases that we call cancer.

Coming out of that project already are incredibly powerful new forms of therapy like Herceptin, like Gleevec, two drugs that are highly targeted. Not the kind of chemotherapy that Mr. Armstrong described that are so extremely toxic, but drugs that are, if you will, smart bombs that go directly to the Achilles heel of particular forms of cancer.

In the intervening years, we have developed a number of additional drugs, and we are finding that progress is much slower. Some of that is because the biology of cancer is very difficult.

A cancer cell differs from a normal cell by mutations, changes in about 200 or 300 genes out of that cell's genome. Our genome has 30,000 genes in it, roughly. The difference is incredibly subtle. Far less than 1 percent of the genes that are changed are the ones that are called cancer.

On the other hand, figuring out which of those 300 changes is the one that if you could turn it around or stop it would cure cancer is an incredibly daunting task. Cancers also trick the body into allowing the cancer to go. Cancers are very subversive cells. They evade and defeat the mechanisms that we have in place to protect ourselves from cancer.

As we think about what needs to be done to control and conquer cancer, I believe, and I think I share this view with my colleagues, that we need both a better way of doing what we already know how to do. That was very much the focus of the last panel, one that we fully endorse and support.

If we were to use, to the maximum that we know how to use it, preventive strategy—smoking cessation, diet, exercise, oral health checks for oral cancers, mammograms, colonoscopy, fecal occult blood stool testing—we clearly, in the short term, could reduce deaths and suffering from cancer enormously.

We also have to balance that and have a balanced portfolio of research. Because there are many forms of cancer for which we don't have yet good preventive or early diagnostic methods, nor do we have the treatments that could be used if we were to detect those cancers. We need better ways to provide therapies that are more effective, that are less toxic, that are usable in patients as they become older. Older patients don't tolerate our existing therapies quite as well as younger patients.

We need better tests—biomarkers we call them in the field—blood tests or breath tests or urine tests that would tell you that

a cancer is developing. Better methods of imaging so that we can see a tumor and know precisely where it is, when the tumor might be 1,000 or 10,000 cells in size rather than over a billion, which is the typical size of a tumor when it is detected even very early. There are already a billion tumor cells in the body.

All of that is going to require basic biological research. It is going to require applied research, focused on the various forms of cancer. It is going to require clinical research and clinical trials because what good does it do if we learn all those things and do not have a good way of finding out whether they matter and are going to be beneficial in people? At some point, we have to be able to study these new agents, the new strategies in people.

We need health services research and nursing research. Nursing research focuses on the experience of the patient as the patient progresses through an illness. Many of the advances that we have made are due to improvements in the quality of life, the way the cancer chemotherapy and surgery and radiation are tolerated, the way that pain is palliated during treatment.

Health services research has to be part of the portfolio because if we were, for example, to initiate a widespread program for colorectal cancer screening, which method would be the best and the most cost-effective and the most likely to detect the cancers that are likely to kill us?

Which test could we find that would be better than the PSA test—a good, but highly imperfect test for screening for prostate cancer—that would tell us not just who has prostate cancer, but which of those patients has the prostate cancer that needs the kind of radical surgery and radiation and drug treatment that we give probably to more patients today than we should because we simply don't know which patients are going to die if we don't do that.

I am here today to advocate that as we look at this holistic view, which I think is visionary on your part, this holistic view of cancer—access, the best use of our existing strategies for early detection, for prevention, for making sure that all patients can access the state-of-the-art in treatment—that I also need to be the one who reminds us that we know so little about so many forms of cancer that we must also make research part of each and every initiative and intervention, whether that research is in the form of public health research, basic biological research, nursing and clinical research, or epidemiology to assess the changes in risk factors. The demographics of cancer are changing rapidly.

Fortunately, lung cancer has actually begun to decline from smoking. But lung cancer in nonsmoking women is increasing. Why is that? What are we going to do about it? What new strategies for detection and treatment for that newer form of cancer that is emerging need to be done?

We will always be contending with the mechanisms that make cancer happen as our population ages and lives in an increasingly more complex and toxic environment.

In closing, I just want to thank you profoundly, for all of the groups that I represent, for your vision and commitment. I want to urge that as we look at all of the ways that we need to attack cancer as a national problem, a public health problem, a problem for individuals and families, that we find a holistic way, as Steve

Case mentioned, to encourage our scientists and investigators to use every opportunity for us to learn, even as we treat the cancers that we face today, so that we will constantly be improving what we have to offer to patients and to their families with cancer.

Thank you very, very much.

[The prepared statement of Dr. Benz follows:]

PREPARED STATEMENT OF EDWARD J. BENZ, JR., M.D.

On behalf of Dana-Farber Cancer Institute, an NCI-designated comprehensive cancer center located in Boston, MA, thank you for inviting me to testify at today's hearing on comprehensive cancer legislation. As a comprehensive cancer center director, I, and the colleagues and patients that I represent, have a deep interest in all aspects of the forthcoming cancer legislation. My distinct role today, however, is to reflect on the essential need for fundamental and applied cancer research. I have had the privilege to serve as the co-chair of a recently-formed Research Working Group, a panel of physicians, scientists, advocates and policy specialists convened to provide expertise and formulate recommendations to revolutionalize the cancer research enterprise. We appreciate the chance to share those recommendations with you now.

A VISION OF THE FUTURE OF CANCER CARE

The world of cancer care is changing before our eyes. The era when treatments were focused on the organ where a cancer originates is coming to an end. In the not-too-distant future, patients may receive therapies geared to the specific molecular characteristics of their disease. These customized treatments could include agents able to block the particular genes and proteins that have gone awry in the cancer tissue. Such agents will be supplemented by others that choke off the blood supply to tumors, limiting their size, and by vaccines that mobilize the body's natural immune defenses against cancer. Still other agents could take aim at the tumor's ability to spread to other parts of the body. The effect of such treatments could be tracked by imaging technology capable of showing, in precise detail, the extent of death of tumor tissue.

Other changes might be just as dramatic. The same knowledge that would enable us to halt the genetic machinery of cancer could lead to agents that can prevent cancer in people at risk for it. We'll hope to have a better handle on why some populations—for genetic, cultural, or economic reasons—have a greater likelihood of getting cancer and lower rates of successful treatment. We expect to know the safety issues associated with each form of treatment and have effective protocols for minimizing them. We'll ensure that the environment in which patients are treated—hospital, clinic, or home—is as responsive to patients' needs and well-being as possible.

Ambitious as all this might sound, the fact is, some elements are already in place, and more are coming on line every year. The completion of the Human Genome Project has spurred the development of several "targeted" therapies that take aim at specific malfunctioning or misbehaving genes. The best-known of these are Herceptin®, which has benefited thousands of women with a specific type of breast cancer, and Gleevec®, which is now the standard of care for many patients with chronic myelogenous leukemia and the digestive tract cancer known as gastrointestinal stromal tumor (GIST), for which there previously was no effective therapy for many patients. Blood vessel-blocking drugs known as angiogenesis inhibitors, such as Avastin®, have become part of the regular arsenal of therapies against several kinds of cancer, including colon cancer. In recent weeks, a study has found that in patients with metastatic melanoma—a condition for which no effective treatment exists—Gleevec can drive the disease into remission if the cancer cells contain a key genetic mutation, or abnormality. These optimistic projections for the future could only happen if we are able to build on the research momentum generated by the human genome project and other advances, which will only happen if research funding growth is restored to at least its historical pace.

THE MANY FORMS OF RESEARCH

The groundwork for all these advances has been laid by an unprecedented degree of research—most of it government-funded—at academic and private institutions across the United States and overseas. A great deal of this exploration has occurred at the level of basic science—in which investigators study the fundamental workings of normal and cancer cells—and clinical science—where potential therapies are tested in human patients—but this represents only a portion of the full spectrum of

cancer research. Equally robust efforts are under way in the areas of cancer prevention, patient safety, quality of care, quality of life, nursing, health disparities, and treatment outcomes. Much of this work necessarily takes place in health centers, but much is done in cooperation with community groups such as employers, religious organizations, tenants' groups, and neighborhood associations.

The reason for this broad focus is that cancer is truly a multi-dimensional problem—first and foremost, a matter of individual health, but one that affects people's loved ones, finances, occupation, education, and community, and one that reverberates on a local, State, and national level. Just as cancer needs to be attacked biologically on a variety of fronts, so does cancer research need to concern itself with all the implications of the disease and its treatment. We will not be able to truly defeat cancer unless we grapple with the entire array of issues associated with the disease.

CANCER'S CONTINUING TOLL

Despite significant and steady gains against cancer—seen most clearly in a slow but uninterrupted decline in U.S. cancer death rates over the past 3 years—the disease continues to take a devastating toll. In 2008, there will be 1.44 million new cases of cancer in the United States (not including more than 1 million new cases of basal and squamous cell skin cancer) and an estimated 565,650 cancer-related deaths, according to the American Cancer Society. The number of new cases, which stood at 1.25 million in 2002, is rising each year as the American population ages. Nor are the physical, emotional, and financial costs of the disease spread evenly across the population: the National Cancer Institute states that the burdens of cancer are "unfairly shouldered by the poor, the elderly, and minority populations." Financially, the annual bill for cancer care in this country exceeds $200 billion.

LAYING THE FOUNDATION

Clearly, an immense amount of work remains before cancer can be declared "conquered." Research over the past two-plus decades has provided a scientific and social foundation from which we as a nation can launch a truly decisive assault on the disease. We know in intricate detail the genes and combinations of genes that cause tumors to form and drive their growth. We know, with equal specificity, the body's responses to the formation and spread of cancer. We have devised ways, in many instances, of blocking these genetic malefactors and the proteins they're responsible for—including the use of sub-microscopic nanoparticles or lab-made proteins that home in on key genes and stifle their activity.

In other facets of the cancer riddle, researchers have developed effective communication techniques and public-service campaigns for informing people—at home, on the job, where they shop, and where they go to school—about how to reduce the risk of cancer. Hospitals have designed systems for ensuring that when patients are treated for cancer, they're treated in the safest possible environment with powerful safeguards against medication errors. Investigators are compiling examples of "best practices"—determining which treatment approaches are most successful and advocating for them to become the standard of care. Other scientists are cataloging the ways that diet and behavior influence people's risk of developing cancer. Still others are charting racial, ethnic, and socioeconomic disparities in people's risk of contracting cancer and their likelihood of receiving proper treatment for it.

The cumulative effect of this work—in the lab, the clinic, and the community—is to place the Nation's cancer research enterprise on the brink of dramatic gains against the disease in the years ahead. In many respects, the work undertaken thus far can be viewed as a down payment on the new generation of therapies now taking shape.

AREAS OF FOCUS

In surveying the state of cancer research in the United States, the Research Working Group has identified a number of problem areas that are impeding optimal progress. Our recommendations offer ways of rectifying those problems and reinvigorating the Nation's overall cancer research effort. We have divided our study into seven broad categories, which we summarize below.

I. Translational Research

The National Cancer Institute-supported effort to convert basic scientific findings into new and better therapies is not keeping pace with the advances in knowledge and technology over the past 40 years in cancer research. Among our recommendations to remedy this situation are: a special funding program to advance a select number of especially promising early research opportunities; joint NCI/industry

funding of collaborative early translational research projects; and increased NCI interaction with foundations and advocacy groups to advance this type of research.

II. Clinical Research

Clinical trials are becoming increasingly complex to conduct, and the NCI's per-patient reimbursements are insufficient to cover the costs of such trials. Among our recommendations: additional Medicare payments to cover the additional time and resources involved in enrolling patients in trials; and group and individual health insurance mandates to cover the routine costs of participation in trials.

III. National Collection of Tissues/Biospecimens

Cutting-edge cancer research is impaired by the absence of either a centralized network of biospecimen and tissue collection banks, or consistent standards for retention and storage of such specimens. Among our recommendations: establishment of a National Cancer Biospecimen Network by linking existing public and private biospecimen and tissue collection banks; and guarantees of protections against genetic discrimination.

IV. Prevention and Early Detection Research

Despite the launching in 2000 of the Early Detection Research Network by the NCI, only a few biomarkers—substances in blood or other fluids that serve as telltale signs of cancer—are routinely used in oncology today. Discovery of new ones is hampered by the limitations of current technology. Among our recommendations: a standard process for developing, testing, and proving the value of biomarkers; support for high-quality biorepositories of samples of cancerous tissue across all stages of development and representative of all cancer sites; and Federal and private health insurance coverage of new biomarker tests.

V. Young Investigator and Oncology Nurse Workforce

Teaching and mentoring the next generation of investigators is one of cancer scientists' most important jobs, but many of today's brightest young researchers are finding it increasingly difficult to establish independent careers in biomedical research and are leaving the field. Equally disturbing trends are threatening the vitality of the oncology nursing workforce, which is critical to quality care for patients. Among our recommendations: more stable funding streams to allow individuals and institutes to better plan projects and careers; more opportunities for non-U.S. citizens to emigrate and compete for training, postdoctoral and research awards; and fully funding for Federal nurse loan repayment and scholarship programs.

VI. Collaboration

There is a lack of collaboration among NCI-funded cancer centers and programs, and a variety of barriers discourage partnerships between publicly and privately funded researchers. Pharmaceutical and biotechnology firms have little financial incentive to develop treatments for rare cancers. Among our recommendations: expansion of the Bayh-Dole Act to permit cancer-related partnerships between academia, nonprofit organizations, and private companies; and remove some restrictions on international sites that participate in NCI-funded trials.

VII. Federal Funding

Ten years ago, the Nation made a bold, 5-year investment in the National Institutes of Health and the National Cancer Institute, the primary Federal vehicle for advancing cancer research. Between 1998 and 2003, NIH appropriations for cancer research essentially doubled, far outpacing the historic norm of 8.2 percent average annual increases. Since that period, however, the budget for such appropriations has been flat or declined. As the accompanying chart shows, had the 5-year doubling never occurred and the 8.2 percent average been maintained each year since 1998, the appropriations budget would be significantly higher than it is today. Funding cuts for extramural research have been even more dramatic if one takes into account the allocations made for other NCI obligations. The result of this fall-off is that many experienced researchers are struggling to obtain funding for more conservative, less-ambitious projects, while young investigators are increasingly abandoning the field. Without a renewed commitment to funding, the potential for new treatments, cures, and prevention strategies for cancer will continue to recede. Among our recommendations: consistent and sustained Federal funding for research; support programs to improve the accuracy, completeness and accessibility of cancer data; and establish an office for rare cancers to ensure that research needs are met.

CONCLUSION

Decades of research have brought us to the point where some of the most dramatic advances in the history of the disease's treatment are coming into sight. The American public has made an investment in cancer research unequalled by that of any other nation, in the hope that such research will lead to better treatments and long-term cures. We have the opportunity, now, to honor that investment by ensuring a level of funding that will bring the promise of current cancer science to fruition.

The Research Working Group encourages the Members of the Senate Committee on Health, Education, Labor, and Pensions to provide the financial, regulatory, and legislative tools to carry the War on Cancer to its decisive stage.

The CHAIRMAN. Thank you very much, Doctor.

Mr. Simon.

STATEMENT OF GREGORY C. SIMON, J.D., PRESIDENT, FASTERCURES, WASHINGTON, DC

Mr. SIMON. Thank you, Senator Kennedy, it is an honor to be here today. I would also like to thank Senator Enzi, who is not here, for reaching out to invite me to testify. I would like to thank all of the Senators for your interest in this very important topic.

I also want to say that our organization is only 5 years old, and there are many people in this town who have fought long and hard to have the war on cancer succeed. I want to thank one of those people who is here today, Ellen Siegel, who is the head of Friends of Cancer Research and is an indefatigable fighter in the war against cancer.

FasterCures is a nonprofit center of the Milken Institute. We are independent. We are nonpartisan. We do not accept funds from drug companies, biotech companies, or device companies so we can maintain our independence. Our mission is to save lives by saving time, time in the research, discovery, and development of cures for diseases of all kinds.

Given the human and financial cost that we suffer from cancer and the emotional and economic gain we would enjoy from curing cancer, no one can say that our current investment of money, human capital, and technology amounts to a war on cancer, much less an effort to win the war. It is not just our investment that is lacking, it is also our strategy.

To paraphrase former Secretary Rumsfeld, we cannot fight this war with the strategy we have. We have to fight this war with the strategy we need. The strategy we have is derived from the 20th century model that underpins the NIH, which is based on a system whose goal is to study human biology. As a result of that system, we are not soldiers in a war against cancer, we are students majoring in cancer.

In the 21st century, our strategy to fight cancer must be based on a system designed to cure diseases. What would this change? Everything. It would change how, where, and why we invest money in cancer research. It would change how we use and share data, biospecimens, intellectual property, human resources, and designed clinical trials. It would change the daily purpose of research from what Michael J. Fox calls "careeriosity" to outcomes-focused research designed to cure patients.

It would target the biggest questions in cancer research with a unified team effort rather than a fragmented bureaucratic infra-

structure. It would require us to give the FDA the budget, the people, and the tools necessary to review expeditiously and thoroughly the new therapies that are so desperately awaited by so many of our loved ones and friends.

It would require us to link, not separate, our researchers in academia, Government, nonprofit, and for-profits in new efforts like the Reagan-Udall Foundation. It would require us to ensure that all Americans enjoy the benefit of new cures and treatments so that where someone lives does not determine whether they live.

In my hometown of Blytheville, AR, my father contracted cancer at the age of 91. There were no cancer doctors in Blytheville, AR. They came over twice a week from Memphis. That was the bad news. The good news was you couldn't get cancer on Monday, Wednesday, or Friday because the doctors were only there on Tuesday and Thursday. We have to provide access to these new cures to all of our citizens regardless of geography and social and economic status.

The first and greatest challenge to curing cancer in the 21st century is to believe we can do it. We have to be willing to challenge long-held assumptions about the nature and purpose of medical research and to share and show a renewed commitment to supporting medical research through meaningful investments of financial and human capital.

A long time ago, a young leader of America, standing in Rice Stadium in Texas issued a challenge. I would like to paraphrase that challenge. Why choose to cure cancer? Why choose that as our goal? Some might say, "why climb the highest mountain? Why, years ago, fly the Atlantic? Why, years ago, walk on the moon? Why does Rice University play Texas?"

We choose to cure cancer not because it is easy, but because it is hard. Let us choose to do it, and let us choose to do it right.

Thank you very much.

[The prepared statement of Mr. Simon follows:]

PREPARED STATEMENT OF GREGORY C. SIMON, J.D.

I. INTRODUCTION

I want to thank the Senate Committee on Health, Education, Labor, and Pensions (HELP) for the opportunity to present testimony today. My name is Greg Simon,[1] and I am the President of *FasterCures/The Center for Accelerating Medical Solutions*, based in Washington, DC.

FasterCures is dedicated to saving lives by saving time. Our mission is to identify ways to accelerate the discovery and development of new therapies for the treatment of deadly and debilitating diseases both in the United States and around the globe. The organization was founded in 2003 under the auspices of the Milken Institute to aggressively catalyze systemic change in cure research and to make the complex machinery that drives breakthroughs in medicine work for all of us faster and more efficiently. During our relatively brief history, *FasterCures* has worked with a broad range of individuals and organizations to eliminate barriers to efficiency

[1] Throughout my own career, I have focused on efforts to advance medical and scientific discovery. Before joining *FasterCures*, I served as the Chief Domestic Policy Advisor to Vice President Al Gore from 1993 to 1997, specifically on economic, science, and technology issues. In that role, I oversaw a number of initiatives, including the programs of the National Institutes of Health, National Cancer Institute, Food and Drug Administration (FDA), the Human Genome Project, and the development of the regulatory framework for biotechnology products. I also had the honor of serving on the staff of a congressional committee. From 1985 to 1991, I was Staff Director of the Investigations and Oversight Subcommittee of the House of Representatives Committee on Science, Space, and Technology.

and effectiveness in our systems of disease prevention, treatment, research, and development.

FasterCures is independent and non-partisan. We do not accept funding from companies that develop pharmaceuticals, biotechnology drugs, or therapeutic medical devices. Our primary mission is to improve the lives of patients by improving the research environment, research resources, and research organizations.

II. ARE WE IN A WAR WITH CANCER?

Our Nation incurs an enormous human and financial cost due to cancer every day. It is expected that cancer will claim over 565,000 Americans in 2008, more than 1,500 people each day. One in two men and one in three women are likely to develop cancer in their lifetime. The annual bill for cancer care in this country exceeds $200 billion. The economic benefit our Nation would enjoy with a 1-percent reduction in cancer mortality would be $500 billion (Murphy and Topel, 2006). Yet our national investment in cancer research is going *down* and is nowhere near commensurate with the costs we bear or the gains we could expect if we made progress in curing cancer.

With those harsh facts as background, no one can claim that our historical and current investments in cancer research or our cancer research strategy itself rises to a level that justifies claiming that we are at war with cancer.

We are not soldiers in a war against cancer; we are students majoring in cancer.

We are not investing the financial resources, human capital, and technological infrastructure needed to be "at war" with cancer, much less to win that war.

III. REORIENTING THE CANCER RESEARCH ENTERPRISE

What is behind the slow momentum in clinical discovery and application? There are many factors, but among them are structural obstacles that have arisen from the ways in which the biomedical research enterprise has grown and evolved along with the Nation's increasing investment in science over the past 50 years. Shortly after World War II, the National Institutes of Health (NIH) created a research enterprise system whose central organizing principle was the study of human biology. Without a doubt, the value of this basic research has revolutionized our understanding of diseases and opened doors of scientific promise beyond anyone's imagination. It is not entirely sufficient to develop a therapy for a patient.

In addition to this system of *studying diseases*, we need to create a medical research enterprise whose central organizing principle is *curing diseases*. Cancer research can be the pathfinder for this new form of biomedical research enterprise. If we can address these problems for cancer, there will be enormous value to the rest of our disease research system.

IV. BREAKING DOWN BARRIERS TO CURING CANCER

The challenges in our current system may not allow us to realize the opportunities in cancer research. The past few decades have brought enormous breakthroughs in the fundamental knowledge necessary to understand, prevent, diagnose, and treat cancer. Yet it still takes an average of 17 years to translate these discoveries into effective treatments. To truly organize our research enterprise around curing cancer, we need to forge solutions to the barriers that stand in our way.

1. Transform the Existing Fragmented, Bureaucratic Research Infrastructure Into a Collaborative Network

Our research environment has created an entire bureaucracy that fuels a quest for research publications, a need for perpetual grant seeking, and an intellectual property protection system that has resulted in a lottery ticket approach to scientific findings. Changing the infrastructure and reward systems within academic research institutions is difficult. There is fierce competition for funds, publications, and patents which serve as a disincentive to institutionalized communication and data exchange between basic and clinical researchers. Scientists have inadequate opportunities for cross-disciplinary training and practice.

2. Move Toward a Systems Research Approach

Currently, we have a highly specialized, reductionist approach to scientific inquiry. There is little funding or reward available for high-risk research. The system tends to focus on individual organizational challenges instead of collaborative approaches to "big picture" problems.

Cancer is a systems problem. It requires the collaboration of multi-disciplinary teams from many institutions and perspectives. At every turn this collaboration is discouraged. NIH grants are still primarily focused on principal investigators, not

teams. Universities throw up legal and financial objections to collaborations with other universities. Major medical journals only give real credit to the first and last authors listed on a paper, thereby discouraging researchers from collaborating for fear they will not receive credit and therefore not move along the road to tenure—one more bad side effect of organizing the system to *study* disease rather than *cure* it.

3. Ensure Scientific Research is More Outcomes Focused

In funding deliberations at the NIH there is little emphasis on specific goals or milestones to cure disease or on achieving specific clinical results. Researchers often insist that science cannot be managed, and that the role of the NIH is to provide ever increasing funds and not to direct how those funds will be used. NIH program officers exercise little oversight over the use of NIH funds except to be sure that researchers are doing the work for which they were funded. As a result, the time from initial discovery to dissemination and commercialization is often measured in decades—an outcome simply unacceptable to the citizens who fund this research and expect to benefit from its fruits.

The NIH Director and the National Cancer Institute (NCI) Director have the authority to start using new goal-oriented funding methods that can accelerate medical research. The National Institutes of Health Research Reform Act of 2006 gave the NIH Director the authority to:

> *". . . allocate funds for the national research institutes and centers to award grants, contracts, or engage in other transactions, for high-impact, cutting edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders."*

Institute Directors, including the head of NCI, have authority under the act to use those allocated funds in novel and creative ways to spur innovation and cutting-edge research.

The obstacle to using this authority is a classic Catch–22. Critics argue against more money for NIH and NCI because of concerns that the budget doubling did not lead to breakthroughs. Using the same old mechanisms to fund low-risk research will not lead to breakthroughs. No one will use the new authority to fund new high-risk research because there is so little money available for the traditional basic research.

We need not only to allow *but to require* the NIH to invest in cutting-edge technologies through goal-oriented, contract funding mechanisms. Intelligence agencies have the ability to invest in start-up companies through their venture capital firm, In-Q-Tel. The Defense Department and NASA have "other contracting authority" to do the same. Why shouldn't the NIH be allowed to, and directed to, invest in the best private sector research tools and approaches, and leverage private sector resources in the same way?

We should integrate, not segregate, translational and clinical research. The message must be clear to all those engaged in NIH-funded research, inside and outside the walls of the Institutes, that the ultimate goal of all research is to improve health and cure disease. Translational research, by definition, requires joining basic research to a therapy that will help a patient. This translation process requires that each researcher understand the source and the ultimate use of the knowledge they are part of creating.

4. Clarify the Purpose of and Measures of Success for Clinical Trials

Human clinical trials are absolutely critical to medical progress. Recruiting volunteers to participate remains one of the costliest aspects of the drug development process. Reducing the length of a clinical trial by just 1 month by improving patient recruitment could not only save lives, but also generate additional revenue to reinvest in the research and discovery of new therapies.

The clinical trial challenges are especially acute in some cancers where clinical trials are viewed as the last hope and often viewed as the only therapeutic option. Staying on the current path is simply not an option if we want to accelerate the search for cancer cures. Some of the ways we can do this include:

- Creating a national Web-based registry of individuals willing to participate in clinical trials;
- Orchestrating a major public relations effort to highlight the critical role patients play in the search for cures and to give them the information they need to get involved;
- Partnering with community physicians to educate them about clinical trials, develop new incentives for their participation, and create "mini-CROs" to ease their administrative burden; and

• Institutionalizing methods for making research protocols more patient-centered such as revamping the informed consent process.

By enrolling in clinical trials to test potential new therapies—as well as by providing tissue samples, blood, or medical histories—patients can provide critical information and resources, without which the search for cures could slow to a halt. *FasterCures* has focused on all three of these tools for discovery under our Patients Helping Doctors (PHD) program.

5. Establish Standards for Biospecimen Collection

We cannot develop therapies *for* us without first conducting research on tissues taken *from* us. The availability of high-quality biospecimens allows a researcher to conduct a wide range of analyses that not only allow for a better understanding of the genetic and molecular changes involved in the progression of diseases, but can also be used for assessing the effectiveness of novel drugs and therapeutics in a particular patient population.

Progress in cancer research will be impeded if we cannot create a network of biospecimen repositories and standardize the collection and storage process. The lack of standards for molecular-based biomedical research as well as standards for the collection of tissue samples, genomic data, and information exchange across private and public sectors curtails collection of much-needed biospecimens. It also means that many of the samples already collected are simply not useful.

We need to support private and public efforts to strengthen the network of biobanks. Biobanks are a critical resource for such molecular-based biomedical research. The data, biospecimens—such as tissue or blood—and molecular components that they collect, test for quality, and then distribute to researchers are absolute requirements in the pathway to developing modern diagnostics and cures for human disease.

The NCI needs to overcome the resistance of local cancer centers and create a unified system of tissue collection and preservation to accelerate medical research.

6. Create Platforms to Address Big Scientific Challenges

The "knowledge economy" has affected all aspects of our lives—except for the most important, our health. In order to build a knowledge economy in health research, we need to find pragmatic models that link researchers and their knowledge into networks that can identify and solve the big problems in cancer research.

The NCI is beginning to address this reality through programs like the "HapMap," The Cancer Genome Atlas, the NCI Alliance for Nanotechnology in Cancer, the Cancer Bioinformatics Grid program (caBIG), and the Translational Research Working Group. These efforts are harbingers of the future direction cancer research must take to create the information infrastructure, databases, and standards necessary to progress.

7. Transform the NIH Intramural Research Program to Focus on Translational Research

All of the research being funded by NIH and conducted at NIH needs to be as efficient as possible. Clearly, additional funds are needed and the impact of declining NIH budgets is already sending a rippling effect across the research infrastructure. We need to be sure that existing programs are maximizing their potential.

The NIH Intramural Research Program (IRP) is a unique national resource. It includes a large cadre of scientists, clinicians, and technicians, supported by long-term and stable funding, an expansive infrastructure, and close proximity to the NIH leadership. It was established over 50 years ago, at a time when there was only a small extramural biomedical research community, and thus its function was unique: both to support multidisciplinary research and train the next generation of researchers. However, as the extramural biomedical research community has developed over time, the IRP's mission and activities are no longer clearly distinct from those of the extramural community.

There is broad consensus that, given its size, scope, and resources, the NIH IRP should not simply be a duplication or extension of the extramural biomedical research enterprise. Rather, it should take on distinctive and strategic research programs that respond to pressing needs and opportunities more in line with its special status. It should function more nimbly, be more responsive to change, and take better advantage of its long-term funding stability and low level of competing demands. Moreover, the juxtaposition of extensive basic and clinical research communities provides great opportunities both for multidisciplinary and translational research, and both should become more clearly central to the IRP's mission.

Moreover, the IRP should become more outcomes-focused, meaning it should strategically seek solutions to clinical problems through combining bench work, animal

models, and human studies. Its focus on basic questions should be more clearly supportive of solving pressing medical problems. The ultimate success of the IRP should be measured both in terms of the quality of the science it conducts and its clear accomplishments contributing to improved health.

To achieve this vision, the culture, expectations, and paradigm of the IRP should be realigned. Such a transformation will require congressional and administrative action and leadership. The NIH Director must be supportive of reform and granted the authority to implement widespread change in the IRP. Leadership should be assessed on its ability to push a priority-setting and review strategy that is more strategic and consistent, coordinating and facilitating the collaboration of the various institutes and centers, and focused more on quality control, assurance, and accountability, as well as on basic, translational, and clinical research progress.

8. Develop a Responsive Peer-Review System

Our current systems for reviewing and funding research, however, have become in many ways highly conservative, placing heavy emphasis on established researchers and high success rates in research outcomes, instead of clinical outcomes. Novel, high-risk proposals do not fare well in a system driven to maximize positive results to get scarce grant funds. The peer-review system is also oriented around evaluating individual proposals and identifying flawed ideas—not around prioritizing research projects for a particular purpose.

NIH is the largest pillar on which the academic peer-review system currently rests, and the impact of any effort at NIH to revamp the system would be wide-ranging. Even simple procedural changes could significantly improve the quality of proposal evaluation (and evaluators) and give more innovative research a better shot at competing for funds.

We believe that assumptions about the integrity and validity of NIH's peer-review system need to be tested to ensure that it is as responsive as possible to scientific and health priorities.

The review system should be designed to identify the most promising areas of scientific exploration in terms of their potential to contribute to improved human health and well-being. This includes basic science studies of normal function and development in both humans and in animal models, translational research that develops drugs or other therapies, and clinical trials that test interventions in patients.

All types of research across this spectrum are critical to the Nation's health. *FasterCures*, however, has concerns that despite incremental improvements to the system over the past few decades, some major challenges remain. These challenges will not be sufficiently addressed by simply re-reviewing the composition and organization of the current system.

9. Encourage Innovative Research Approaches and New Models of Research Funding

Together, the public and private sectors can transform our research and healthcare system from the current model to an integrated, information-based, high-quality, health-sustaining model that will extend and improve the quality of life for patients with cancer in the 21st Century.

Free of the imperatives of publication and career advancement in academia and the bottomline imperatives of the private sector, disease research organizations are ideally positioned to make relatively high-risk investments that could significantly move a field of disease research forward and increase the likelihood that other parties will invest as well. Venture philanthropy groups such as the Multiple Myeloma Research Foundation, Susan G. Komen for the Cure, Prostate Cancer Foundation, and the newly created Melanoma Research Alliance have been at the forefront of creating new models of collaboration and public-private partnerships that can "de-risk" the costly process of therapy development.

At *FasterCures*, we work with many of these groups both in the cancer and non-cancer arenas. They have a unique ability to move research forward by targeting research in areas that will help translate basic scientific discoveries into therapies, such as biomarkers, target and pathway validation, animal models, and small pilot clinical trials. They also:

- Bring a business mindset to the conduct of research;
- Create funding mechanisms that enable or even require academic researchers to work with industry partners;
- Provide access to a patient—community and resources—by creating patient registries, biorepositories, and networks of trained clinical trials sites;
- Explore new indications for existing drugs;
- Employ high-throughput screening to help industry identify better investment opportunities;
- Facilitate access to scientific experts and clinicians;

• Educate industry about the state of understanding of and research into a specific disease;
• Advocate with the Food and Drug Administration (FDA) for approval of new treatments; and
• Serve as a "Good Housekeeping Seal of Approval" validating particular researchers or paths of inquiry.

10. Collaborate With, and Support for, the FDA

In the past 10 years, we have witnessed dramatic advances in science that impact the practice of medicine, including the mapping of the human genome, and advances in computational tools and broadband communications. Electronic health records will likely change the practice of medicine and hopefully clinical research in the coming decade, and offer substantial benefits to monitoring adverse events.

Despite these advances, the FDA's ability to harness these advances has been hampered because the budget has not kept pace. In fact, it is currently at a level that is the same in real dollars as in 1996. Each year, FDA receives minimal new dollars and yet their costs increase, missions evolve, scope of science expands, and inflation erodes this budget. In addition, new initiatives of the FDA such as the Critical Path Initiative have not been given full financial support. The budget is holding the FDA back and preventing the agency from maximizing the benefits of these historical advances in science for the American public.

The FDA plays a central role in American medicine—protecting and promoting the public's health. The agency must ensure that products are safe, but also effective. It must help speed lifesaving drugs to patients, yet ensure those same patients have the safest drugs possible. We ask a lot of the FDA and we expect a lot. But we don't support it a lot. The FDA, charged with protecting 300 million people, has a budget that mirrors that of the school budget in Montgomery County Maryland.

FDA needs increased appropriations from Congress and should not be forced to rely on industry user fees which the FDA is largely restricted from using on post-approval activities. Many of the improvements recommended by the recent Science Board Report, Institute of Medicine report, and included in several legislative proposals will simply not be possible without additional resources. New initiatives of the FDA such as the Critical Path Initiative and the Reagan-Udall Foundation have not been given full financial support—or in the case of the Reagan-Udall Foundation *any support*. We cannot fund the fight against cancer because we cannot end the fights about funds inside the Beltway.

V. ENSURING ACCESS TO CANCER CARE

Our efforts to deliver good cancer care show the same mismatch to the challenge of defeating cancer that we find in our investments and our research strategy. We offer the best care at major cancer centers and academic health centers that are successful at getting Federal grants. Unfortunately, most people do not receive their cancer care at such centers. Many people are treated at local oncology practices and community cancer centers, where resources and cancer doctors are scarce and, regrettably, cancer guidelines for best care are often even scarcer.

We must ensure that *where* people live does not determine *whether* they live. All cancer patients should have access to the best standards of care possible. One approach starts with the NCI Community Cancer Centers Program, a 3-year pilot program to test the concept of a national network of community cancer centers to expand cancer research and deliver the latest, most advanced cancer care to a greater number of Americans in the communities in which they live.

The program brings more Americans into a system of high-quality cancer care, increases participation in clinical trials, reduces cancer healthcare disparities, and improves information sharing among community cancer centers. We should expand the pilot program to include community cancer centers beyond the NCI-designated cancer centers.

VI. CONCLUSION

The first and greatest challenge to curing cancer in the 21st Century is to believe it can be done. We have not given ourselves a chance to prove it is possible because our system is not focused on curing diseases like cancer. We have created an elaborate and complicated system of studying diseases that affects the way we make grants, give tenure, publish data, do clinical trials, create and use intellectual property and train young investigators. If we are to create a 21st Century system to cure diseases, we have to be willing to challenge long-held assumptions about the nature and purpose of medical research and to show a renewed commitment to supporting medical research through meaningful investments of financial and human capital.

SUMMARY—PRESENTED BY GREGORY C. SIMON, J.D., PRESIDENT, *FasterCures*[1]

Are We in a War with Cancer? *We are not soldiers in a war against cancer; we are students majoring in cancer.* We are not investing the financial resources, human capital, and technological infrastructure needed to be "at war" with cancer, much less to win that war.

Reorienting the Cancer Research Enterprise. The central organizing principle of the National Institutes of Health (NIH) is to study human biology. This has led to great advances in knowledge of human health and disease; but it is not a good system for developing therapies for patients. We need to create a medical research enterprise whose central organizing principle is *curing diseases*. If we can address these problems for cancer, there will be enormous value to the rest of our disease research system.

Breaking Down Barriers to Curing Cancer. To truly organize our research enterprise around curing cancer, we need to forge solutions to the barriers that stand in our way.

1. Transform the existing fragmented, bureaucratic research infrastructure into a collaborative network.
2. Move toward a systems research approach.
3. Ensure scientific research is more outcomes-focused.
4. Clarify the purpose of and measures of success for clinical trials.
5. Establish standards for biospecimen collection.
6. Create platforms to address big scientific challenges.
7. Transform the NIH Intramural Research Program to focus on translational research.
8. Develop a responsive peer-review system.
9. Encourage innovative research approaches and new models of research funding.
10. Increase collaboration with, and support for, the FDA.

Ensuring Access to Cancer Care. We must ensure that *where* people live does not determine *whether* they live. All cancer patients should have access to the best standards of care possible.

The first and greatest challenge to curing cancer in the 21st Century is to believe it can be done. We have not given ourselves a chance to prove it is possible because our system is not focused on curing diseases like cancer. We have created an elaborate and complicated system of studying diseases that affects the way we make grants, give tenure, publish data, do clinical trials, create and use intellectual property, and train young investigators. If we are to create a 21st Century system to cure diseases, we have to be willing to challenge long-held assumptions about the nature and purpose of medical research and to show a renewed commitment to supporting medical research through meaningful investments of financial and human capital.

STATEMENT OF HALA MODDELMOG, M.A., CEO, SUSAN G. KOMEN FOUNDATION, DALLAS, TX

Ms. MODDELMOG. Thank you, Mr. Chairman. Senator Kennedy, Senator Murkowski, and Senator Burr, thank you so much for having me.

I come here today as a cancer survivor, as a wife, as a mother, as the leader of the largest breast cancer organization in the world, and it is important, and I am proud to be here for Susan G. Komen for the Cure. It is much more important that I am here in concert with the other groups who work on this disease day in and day out. They appreciate what you have done. We all appreciate what you will do in this fight.

[1] *FasterCures* is dedicated to saving lives by saving time. Our mission is to identify ways to accelerate the discovery and development of new therapies for the treatment of deadly and debilitating diseases both in the United States and around the globe. The organization was founded in 2003 under the auspices of the Milken Institute to aggressively catalyze systemic change in cure research and to make the complex machinery that drives breakthroughs in medicine work for all of us faster and more efficiently. *FasterCures* is independent and non-partisan. We do not accept funding from companies that develop pharmaceuticals, biotechnology drugs, or therapeutic medical devices. Our primary mission is to improve the lives of patients by improving the research environment, research resources, and research organizations.

I guess there is a chance that some of the past attempts that we have had to work on cancer in Congress may have been thwarted because it was about specific body parts. Again, I am especially glad that today I feel like we are coming here together to talk about this. The balkanization of body parts is not necessary, and the thing that is necessary is treating this as an inhibitor.

Twenty-five years ago, Susan G. Komen for the Cure was started by Nancy Brinker with a promise to her sister that she would do everything in her power to end this disease. A billion dollars later, 25 years later, it is with great happiness, of course, that I can report that with breast cancer, if it is found early—and it is about this early detection that I want to talk a bit today—that 98 percent of the women live. Twenty-five years ago, it was 77 percent.

The problem is that there are so many cancers that don't have any effective early detection methods, and that is what we have to stop and we have to start to do. The early detection in many cases is really the closest thing that we have to a cure. We can't really let anything get in the way of fighting this critical battle for biomarkers, these blood tests that Dr. Benz mentioned, the things that make it easy to detect early and actually save people's lives.

We have been talking about this a bit as a colossal cancer crusade. It is time to launch that crusade. It is time to conquer cancer. It is time to unleash the amazing power of science, of technology, of medicine to find these early breakthroughs, the early breakthroughs and early detection.

We want to be able to think about detection that it could be as simple as an injection, where the treatment is so targeted that we don't have to worry about the toxic effects. Here is where we have to stop and remind ourselves about the fact that the early detection methods we have today are not being sought out and not being offered to literally millions of Americans.

We, unfortunately, at Komen have the opportunity to talk to many people who don't have insurance, who are having access issues. One thing that I want to urge, as we talk about the surge in the science and we talk about the biomarkers and we talk about moving ahead, that we talk about at the same time the access issues. Because if we don't talk about them together, the gaps we have in disparities of care will only widen, and I know we know those gaps are there.

It has already been said several times today in several different ways, but 1,500 people, 1,500 Americans die every day from cancer. Sixty percent—you are 60 percent more likely to die if you are uninsured. That is an access issue. The price tag for this is $219 billion a year. If we had access for everybody, the price tag would be even bigger.

The early breast and cervical act has been discussed here today, and it is a wonderful act, and we are very happy about it. The truth of the matter is it is only funded at 20 percent for people that are eligible to get it. Even with the legislation that we have in place, we don't have the funding for even the methodologies that we have today. If we don't stop and work on the access issue at the same time we work on the science, we will be missing an opportunity.

I have to tell you a couple of things that will sound pretty shocking, I am afraid. We have had some rural doctors sort of whisper in our ears that there are many times that a woman in communities where healthcare is not readily available will get a double mastectomy because that woman can't come to the hospital for chemo. She either can't get there because she doesn't have the transportation, or if she does have the transportation, she can't take the time off from work because she is working a minimum wage job and she won't be able to feed her kids, and/or there are no opportunities for childcare for her kids.

When people are choosing mutilation of their bodies versus the treatment that, again, is available today, we really have to stop and understand that piece again as the science surges.

Another thing that happens in our world and another thing that gets told to us is that there are cultural barriers that prevent this access. In some cases, even when the money is there and the ability to get the care is there, Latina women will tell us that they don't want to know about breast cancer because they are afraid that their husbands will leave them. Again, as we talk about access, again, as we talk about biomarkers and the science, we also have to work on the cultural issues.

As Elizabeth Edwards said, we at Komen are spending our research dollars on what we hope and believe is innovative research. We have actually just assigned quite a bit of money, grants, upwards of $7.5 million that charge groups with being co-PIs, having people work collaboratively from separate institutions. It is an issue that has already been brought up today. It is about trying to drive incentives that fix the research system, and that is something we are committed to at Komen as well.

One of the other things that I have discovered when I have had the opportunity to travel around the world with Komen is that the power in health diplomacy, the power to export what we learn from our health system and from our care and from our science is transformative. I take a lot of pride that what we are doing here today, what you are doing here today will create things for us that we can export around the world, and we will be thanked and loved for that. I have seen it personally when we have had the opportunity to do it.

As advocates, we certainly can't deny the complexity of the disease. We can't forget about that. We don't mean to sound naïve. If you think back to the panel who was here before with Steve Case and the fact that America has been founded on solving complex issues, founded on getting creative, founded on technologically driven solutions, we believe and this gives us faith that we can do this. We are not afraid of the complexity, and as advocates, we are going to push forward.

One thing that I also want to say is that, ironically, yesterday I had the opportunity to meet two extraordinary women who were Stage 4. I have to say that my reaction was that I was embarrassed and ashamed that we are not faster, that we are not doing something bigger, that we are not doing something bolder.

These women were angry. They were sad. Their main message was do something about this for my children. It would have been a really difficult night to go to sleep having faced that, but knowing

that we were going to all have an opportunity to come here today and have an opportunity to work with you and what you are trying to do made me feel not as distressed.

This is big. We appreciate it. We love what you are trying to do, and anything that we can do, all of the cancer organizations, we stand ready to do it.

With your indulgence, I would like to just do one more thing. I am going to ask our entire audience to stand up, please. Now I am going to ask every other person to sit down. If you can't figure it out, there are some women who can show you how at the front. Every other person sits down.

OK. For those that are standing, that is roughly the number of people that will be diagnosed with cancer in their lifetime. One in two men, one in three women. For the people that are sitting down, if you look to your right and you look to your left, that is your sister, it is your mother, it is your brother, your friend, or your child.

Thank you for this visual.

[The prepared statement of Ms. Moddelmog follows:]

PREPARED STATEMENT OF HALA MODDELMOG, M.A.

Mr. Chairman, Ranking Member, and members of the committee, thank you for the opportunity to testify before you today about the need for comprehensive legislation to address our Nation's cancer crisis. My name is Hala Moddelmog, and I am President and CEO of Susan G. Komen for the Cure. While I am here in my role as President and CEO of Komen for the Cure, I speak on behalf of every cancer patient who has a stake in finding a cure for this disease and every patient advocate who has dedicated his or her life to ending cancer forever. I am a breast cancer survivor. I joined Komen in September 2006—5 years to the week after my surgery—after a successful career in corporate America, most recently as president of a major food service company. Of all the jobs I've ever had, this—I firmly believe—is the most important of my life. I wake up every day with a purpose: to help put an end to a disease that has affected me and so many others, a disease that cost the lives of countless mothers. It is important for us to remember, on Mothers Day this weekend, how many mothers have been lost to breast cancer and all cancers, how many children have lost their mothers to this terrible disease.

Now is a turning point for the cancer community—we have come together to offer our suggestions and have advocated in unity for change. We are committed to moving beyond strategies that have focused on specific cancers and have limited attempts by Congress to comprehensively address all cancers. We are committed to speaking with a renewed and resounding single voice that calls for action now to end for all time the ugly reality of this disease, which kills 1,500 Americans every day. Because of this, any legislative effort will be that much more powerful, that much more comprehensive, and that much more effective.

MISSION OF SUSAN G. KOMEN FOR THE CURE

Susan G. Komen for the Cure began with a promise from Nancy G. Brinker to her dying sister Suzy that she would do everything in her power to end breast cancer forever. In 1982, that promise became Susan G. Komen for the Cure and launched the global breast cancer movement. Today, Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Komen Race for the Cure, in its first 25 years, Komen for the Cure invested $1 billion to fulfill its promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world. To continue this progress, Komen for the Cure has pledged to invest another $2 billion by 2017.

With $100 million in scientific research grants awarded this year, we are well on our way to meeting our $2 billion goal. This is the largest single-year investment in research in the organization's 26-year history and represents a landmark 30 percent increase over last year's award total of $77 million. With this year's slate of 143 grants, Komen for the Cure has fully activated new funding mechanisms designed to speed the discovery and delivery of the cures for breast cancer. The 2008

slate funds projects designed to promote breast cancer research collaboration and cost efficiencies, arrive at reliable and replicable research results more quickly, motivate bright young investigators to commit to breast cancer research careers and keep career researchers intensely focused on breast cancer. We've made it clear that our money will fund projects that focus on ways to significantly reduce breast cancer incidence and mortality within the next 10 years.

While we invest in research to discover the cures of the future, we must ensure that everyone has access to the best cures we have today. We accomplish this through the community grant programs of our network of 122 affiliates in the United States. Last year Komen for the Cure provided community grants to over 1,600 organizations, totaling over $70 million. These funds provided over 180,000 women with free or low-cost mammograms, helped 18,000 with the physical, emotional, and financial effects of breast cancer treatment, and helped over 4,000 people enroll in breast cancer clinical trials. Many affiliates fund treatment assistance programs that help breast cancer patients with day-to-day chores and provide monetary assistance with rent, utilities, and co-pays. Sadly, for women with advanced breast cancer, Komen grants help provide the legal assistance necessary to help these women put their affairs in order.

Through the newly formed sister organization, the Susan G. Komen for the Cure Advocacy Alliance, Komen for the Cure is taking the next logical next step in its evolution: expanding its reach in the health policy arena. The Komen Advocacy Alliance is directly engaging policymakers and opinion leaders to advocate for increased funding for cancer research and greater access to cancer screening and treatment. Our goal is to expand on the long history of Komen for the Cure's commitment to saving lives through public policy advocacy.

THE CANCER "CRISIS"

I am honored to be testifying today about the need for comprehensive legislation to address the cancer crisis our Nation is facing. We are facing a cancer crisis. A crisis in our investment in prevention and early detection of cancers; a crisis in our dedication to innovative cancer research; and a crisis in patient access to the highest quality cancer care and treatment.

Approximately 40 percent of Americans will be diagnosed with cancer at some point in their lives. More than 1.4 million new cancer cases will be diagnosed in the United States in 2008, and approximately 565,000 Americans will die from cancer this year. The National Institutes of Health (NIH) estimates the annual costs of cancer to be $219 billion. Yet, despite a few highly successful cancer therapies, the fundamental goal of the "War on Cancer" launched in the 1970s—to diminish death and suffering—remains largely unrealized. In the 35 years since the declaration of the War on Cancer, scientific research has produced an abundance of extraordinary knowledge about the biochemical mechanisms that cause cancer. This new scientific knowledge has led to only a modest reduction in overall age-adjusted cancer mortality rates, especially compared to the plummeting mortality rates for cardiovascular disease and stroke. Cancer now exceeds heart disease as the leading cause of death among people under 85 years old.

Through our Komen Community Challenge tour, a nationwide year-long campaign designed to bring communities and policymakers together to close the gaps in access to care, I have heard firsthand from patients, family members, and lawmakers just how severe this cancer crisis is. The impact of cancer on the lives of ordinary citizens is extraordinary, but often unimaginable to those who have not lived through it.

One of the more poignant moments of the Komen Community Challenge was in California. In Sacramento, actor Ricardo Chivara joined us at a rally to motivate the California legislature to expand access to early detection programs. Ricardo shared his reasons for being a breast cancer activist. He said, "I personally know that cancer does not only affect the victim, it also affects his or her entire family. Mothers with breast cancer have an uncertain future for themselves and their children. Sick mothers cannot nurture and guide their children. Mothers suffering from breast cancer sometimes can't even make it to the grocery store to buy food to make dinner, or help you with that evening's homework. I remember on more than one occasion having to ride my bike several blocks with a $20 bill to the grocery store to buy food, put it in my back pack, and ride back home. I was 12. I remember my older sister balancing my mother's check book and paying all the medical bills, because my mother was vomiting from just having received chemo[therapy]. My sister was 15." Ricardo lost his mother, Elizabeth Ries Chivara to breast and cervical cancer when he was 16 years old, and he is an activist because he does not want to see other children suffer the way he and his sisters did.

In California, we also met Jamie Ledezma, a deputy district attorney from Fresno, who was 27 years old and 14 weeks pregnant when she was diagnosed with breast cancer on Valentines Day. Determined not to let her cancer diagnosis stop her dream of being a mother, Jamie underwent 6 months of chemotherapy during her pregnancy. Her son Blake was born healthy, with a full head of hair, and he accompanied his mother to Sacramento to help lobby California legislators. When Blake was a just a month and a half old, Jamie underwent a bilateral mastectomy. Jamie has a significant family history of breast cancer and tested positive for BRCA1. She is a breast cancer activist because she wants to ensure that legislation, such as the recently-passed Genetic Information Nondiscrimination Act, benefits her family.

In Massachusetts just last month, we met Cristina Moya, a lawyer who moved to the United States in 2000 from the Dominican Republic. In April 2005, she found a lump in her breast. She waited 2 months to see a specialist, who assured her that she had nothing to worry about. She did worry, because she had lost her sister to breast cancer and her mother to ovarian cancer. Two months later, she saw yet another specialist, who again told her she had nothing to worry about. She continued advocating for herself, and finally in January 2006, 9 months after she found the lump, she was diagnosed with breast cancer. She was fortunate to have health insurance and was treated at Dana-Farber Cancer Institute, where she had a patient navigator to help her through her treatment. Now she works as a case manager at Jamaica Plain Child Care Center. As a volunteer with the Boston Public Health Commission, Cristina trains women on breast health and the importance of early detection and screening. She said, "I want to help other women, especially women in the Latina community. In many parts of my community, cancer is considered a punishment from God. Women need to know this is a disease that you get treated. No shame should be associated with it."

Cancer is a devastating diagnosis. I learn this every day in my own life, and every time I meet survivors and family members of survivors. From our work with activists, scientists, States and the Federal Government, Komen for the Cure believes that the fundamental gaps in the paradigm of cancer research and care are based on:

- Lack of investment in early detection of cancer;
- Inadequate funding for cancer research and barriers that is difficult to translate basic research into patient treatments; and
- Inconsistent access to high quality cancer care.

To discover and deliver the cures for cancer, we must address these gaps.

EARLY DETECTION OF CANCER SAVES LIVES

Komen has long believed that early detection is critical to successfully treating cancer and has been a champion of early detection programs. Timely mammography screening of women over age 40 could reduce mortality by 20 to 35 percent. Moreover, the 5-year survival rate for women with early-stage breast cancer is 98 percent; for women with distant metastatic disease, the figure plummets to 27 percent. Early detection of prostate and colon cancers is similarly beneficial for patients: the 5-year survival for colon cancer is 90 percent when detected early, and the 5-year survival rate for prostate cancer approaches 100 percent due to early diagnosis and improvements in treatment.

There is no doubt that early detection saves lives. The single most important factor in the relative success of a cancer treatment regimen is often the stage at which the cancer is diagnosed. However, despite the expansion of screening programs in recent years as the result of greater awareness of the importance of early detection, 45 percent of all women over 40—the age after which the National Cancer Institute (NCI) recommends an annual mammogram—still do not receive an annual mammogram. Screening for colorectal cancer is similarly disturbing. Despite the high survival rate of patients when colorectal cancer is discovered early, only 39 percent of cases are diagnosed at the early, localized stage. According to the American Cancer Society, of the 49,960 people expected to die of colorectal cancers in 2008, appropriate testing could save more than half.

In the breast cancer community, we have advanced screening and imaging techniques which can accurately identify the early stages of cancer. For many other cancers there are no such early detection modalities. Ovarian cancer is a particularly devastating example: there is no screening diagnostic, thus a diagnosis is most often made after the cancer has spread when a symptomatic patient presents to her physician. According to the American Cancer Society, when ovarian cancer is detected locally, the survival rate is 92 percent; however, only 19 percent of cases are detected at this stage, and the overall 5-year survival rate is only 45 percent. Survival rates are even more disturbing for lung and pancreatic cancers. In addition to im-

proved education and outreach for current diagnostic screening, the wave of the future lies in the discovery of biomarkers and the development of effective early detection diagnostics for all cancers. Armed with these biomarkers and early detection tools, we must also apply our knowledge of genomic and molecular data to the development of targeted, low-toxicity medications and dosing regimens that are tailored to an individual patient's genetic makeup.

Personalized medicine holds enormous potential to advance oncology care and treatment. With the discovery and clinical uptake of targeted diagnostics and therapeutics, we could save countless lives and reduce untold suffering. We must dedicate substantial resources to the development of biomarkers and to the delivery of personalized medicine.

Continued Commitment to NIH Funded-Research

Previous investments in research have allowed us to make significant progress toward discovering and delivering the cures for cancer. The "doubling" of the National Institutes of Health (NIH) budget from 1998–2003 fostered incredible advances in our understanding of the molecular etiology of the disease. Yet, since 2003, the NIH has been consistently flat funded. When adjusted for inflation, flat funding translates to an actual decline in NIH purchasing power. According to the NCI, when funding is adjusted to reflect the Biomedical Research and Development Price Index, the NCI has experienced a significant loss in purchasing power each year since 2004, resulting in a 19 percent—or $1 billion—loss for fiscal year 2008. We cannot engage in cutting edge science and maintain our status as the global leader in biomedical research without adequate NIH funding.

Susan G. Komen for the Cure is particularly concerned with funding for young researchers. According to recent statistics from "A Broken Pipeline: Flat Funding of the NIH Puts a Generation of Science at Risk," only one in four NIH grants is awarded to a first-time grantee. Young investigators are often the source of the most innovative, creative ideas in science, but we are losing a generation of young researchers due to chronic under-funding of the NIH. The NIH must re-evaluate its commitment to young researchers by creating dedicated funding streams for young scientists, establishing mentoring programs and restructuring the grant review process to encourage funding for high risk proposals sponsored by young, but highly qualified, investigators.

Komen for the Cure is also concerned that the proliferation of basic scientific knowledge about cancer has not been matched by the capacity of the American cancer research enterprise to translate that knowledge into improved diagnosis and treatment. For example, the NCI-supported translational research enterprise is not keeping pace with the enormous opportunities presented by advances in knowledge and technology in the last four decades of cancer research. Advances in basic science are critical, but just as important is the translation of those discoveries into treatments and therapies to benefit patients. To improve the translational research framework at NIH and NCI, we should expand methods for identification of the most promising early translational research opportunities, streamline intellectual property agreements to facilitate collaborative research, and develop standards for storage and access to biospecimens to assist translational researchers. The Institute should also provide opportunities for young researchers to engage in translational research.

Komen for the Cure also encourages the establishment of public-private partnerships to advance translational research. Komen believes strongly that collaboration is the best way to advance scientific discoveries. Collaboration eliminates duplication of effort and allows individuals to benefit from the pioneering ideas of others. Komen for the Cure's own recent focus on partnerships and sponsored programs has resulted in highly visible and productive relationships with the American Association for Cancer Research, with whom we are partnering to create public efforts that address disparities in general cancer research, cancer prevention and breast cancer research; and with the American Society of Clinical Oncology, with whom we are creating programs to look at the quality of cancer care across all regions of this country. Komen also led an effort to bring all key opinion leaders in breast cancer together for the first Collaborative Breast Cancer Summit, held in November 2007. The meeting facilitated discussion around eliminating duplication of effort, sharing information and resources and creating collaborative programs to fund broad initiatives. Partnerships between the NIH and private industry, non-profit organizations, universities, and others could be equally beneficial as we work toward finding a cure for cancer. Komen encourages the development of incentives to foster collaborative efforts as well as the removal of barriers that hinder such relationships.

ENSURING ACCESS TO HIGH QUALITY CANCER CARE

Komen for the Cure has dedicated itself to ensuring that all women have access to high quality cancer care. We believe that all women deserve access to the highest quality treatment and care, regardless of race, ethnicity, socio-economic status or geographic location. Unfortunately, many of these factors do play a role in the quality of care a patient receives—for breast cancer, and for all cancers. For every person with cancer who has benefited from early detection and the best available care, there are many others who have not, and will not, benefit from the advances we have made over the past 25 years. For example, African-American women have a 35 percent higher rate of mortality from breast cancer than Caucasian women, despite overall lower rates of incidence of breast cancer. Only 38 percent of Hispanic women over the age of 40 receive regular mammograms. Those who live in rural communities may have to travel long distances for screening or treatment. And, for all cancers combined, uninsured patients are 60 percent more likely to die than their insured counterparts.

Last fall, the *Wall Street Journal* profiled Shirley Loewe, who was working as a hairdresser when she was diagnosed with breast cancer in 2003. Unfortunately, Shirley did not have health insurance and went to the wrong clinic for her screening and diagnosis. As a result, she was unable to access Medicaid to help with her treatment. After 3 years of delays in treatment and care patched together through multiple sources, Shirley succumbed to the disease last summer, leaving her daughter Niko Ferguson and her children without their mother and grandmother. Niko runs in the Komen Denver Race for the Cure in honor of her mother. Sadly, Shirley is only one of many deserving patients who do not have access to cancer care.

Komen's first annual "State of Breast Cancer Report," which was released in 2007, found that disparities in care were pervasive throughout the continuum of cancer: from unequal representation in clinical trials to disparities in access to early detection services and high quality treatment. A recent study showed that ethnic and racial minorities make up only 10 percent of participants in clinical trials testing cancer drugs. Low-income women and women living in rural areas have difficulty getting to mammography facilities and often do not receive regular screening mammograms. Language barriers and lack of insurance prevent many other women from receiving appropriate treatment for their cancer.

These disparities are not unique to breast cancer and must be addressed if we are to find and deliver the cure to every deserving American. We must provide access to high quality care to every cancer patient. To ensure that research is applicable to both genders and to all ages and racial minorities, the NIH should promote participation in clinical trials by addressing the financial and regulatory barriers that make it challenging for oncologists to offer clinical trials in their practices, including encouraging inclusion of minorities and other under-represented groups as a condition of reimbursement for clinical trials. To ensure equal access to early detection and screening services, we must continue to educate about the importance of early detection and consistently fund early detection programs and early detection research. To ensure access to high quality treatment of cancer, we should strive toward culturally sensitive and coordinated oncology care. Patient navigation services are one critical component to addressing barriers to quality cancer care, particularly for minority and underserved patients who often do not speak English, have low literacy skills, are uninsured and/or live long distances from treatment centers. These patients have difficulty accessing quality care and have trouble coordinating their cancer care, leading to disjointed treatment, inadequate patient-doctor communication, difficulty with follow-up appointments and poor adherence to treatment regimens. Patient navigators help patients "navigate" the maze of doctors, insurers and patient support groups.

Thank you for this opportunity to testify. I have offered only a few of the many suggestions, changes and improvements we must make to address the Nation's cancer crisis. On behalf of Komen for the Cure and the many cancer patient advocacy groups who are working tirelessly to find a cure for cancer, let us together meet the challenge of directing our research efforts toward the detection of cancer at its earliest stages when our chances of stopping it are the highest. Komen's mission is to reduce mortality from breast cancer, but we cannot improve the survival rate from breast cancer, or all cancers for that matter, without investment in early detection of cancer biomarkers. We must devote time, energy and resources to discovering breakthrough, next generation measures for the early detection of cancer and for predicting its behavior before the cancer has spread. We must also continue the promising research on developing tailored therapies to treat individual advanced cancers that have already spread. Personalized medicine is the cornerstone to suc-

cessful treatment of cancer. An accurate diagnosis at the earliest possible moment is critical to successful treatment.

A second challenge is to ensure that every cancer patient in America has access to high quality, affordable care that meets the highest standards set by experts and physician societies. It is unconscionable that we cannot guarantee every American access to lifesaving medical care and unacceptable that we have not addressed this issue.

We come here today to respectfully challenge you to join us, along with the rest of the cancer community, to act boldly, comprehensively, across all fronts—research, prevention, early detection, access and treatment—to win the fight against cancer, and with it, save the lives of millions of Americans.

The CHAIRMAN. Thank you very much, Hala, for your testimony. I couldn't agree more about the potential in terms of what progress, shared progress in the world would mean. We have seen at other times when America has been at its best, particularly in the areas of food, for example, medicines.

You look at what happened when the tsunami hit, where we were so involved, and the opinions about America went up, just soared. We obviously weren't there just for the poll results, but people do have enormous appreciation, as we all would understand, as they are trying to provide help and assistance to their children and to their families.

Let me come back to Dr. Benz and Mr. Simon. When we had the war on cancer, there was that legitimate discussion and debate and editorials about we can't legislate the cure. We understand that. Those that actually opposed the legislation at that time saying that they were opposing it because that is really what they were attempting to do, which is not what we were doing.

We had reached the judgment decision that about two thirds of the funds were going to be basic and about a third were going to be both clinical and more targeted. That was basically a reflection of some of the deep interest that many, many families had, many Americans had, maybe mistakenly, that they ought to have at least some voice in the allocations of resources.

If they are going to be affected by the HIV and AIDS or they are going to beat breast cancer, they want some additional kind of input and impact on this, some additional kind of focus and attention. Looking back, there were some failures, but there also were some successes. Heart disease, stroke, HIV, some results on it. With the others, basic research were going to be peer reviewed.

Now I don't know what is out there. I think all of us are very conscious of the fact that we can't have the "disease of the month," and solving all of our problems. At least I happen to believe that people care and care deeply about some of these issues. We ought to have a broad context, but we should also give some degree, I can't say precisely what percent, by looking into some of these areas that are of particular concern to families.

There has been a strong effort by Dr. Zerhouni to try and bring together these various disciplines, and that was included in the NIH in the last year. He hasn't gotten a lot of resources to be able to do that, but at least he is attempting and particularly in the areas of clinical research, which I think are very interesting. Strong support, and I hope we can get him some additional help and assistance in this.

What is your own kind of sense? We have seen, Dr. Benz, you are familiar with this and as a participant. I know Mr. Simon has

got some real concerns. The concerns have been expressed by members of this committee as well. Obviously, we are all trying to come at this in the way that we can get the best opportunity for making progress with these diseases and to try to do it with the greatest degree of support.

Dr. Benz.

Dr. BENZ. Thank you for the question. It is a great question.

First, I will just mention that one of my present roles is to be advisor to Dr. Zerhouni and his advisory board for clinical research. I chair that committee and have watched what he has been trying to do, and I think it is exemplary of what we face in terms of the systems we have in place now and the need to look hard at those systems to break down the kinds of barriers that artificially divide basic and clinical research, artificially divide research on pancreatic cancer from research on breast cancer.

I will answer your question first as a scientist and tell you that science is completely changing the way we classify tumors. Perhaps the most important classification is in what category should your tumor be in terms of how it is treated?

The drug Gleevec that we have mentioned several times here, the prototype of a new targeted, less toxic form of therapy was developed for a disease called chronic myelogenous leukemia. That drug turns out to be highly effective in a form of sarcoma called GIST sarcoma, which previous to the use of Gleevec was completely untreatable unless caught at a very early stage—treatable surgically.

It now appears that a form of melanoma might be treatable by that drug and yet another form of lung cancer. Now these are minorities of each group of patients, relatively small percentages of each group of patients. In the aggregate, a large number of patients benefit enormously from this drug because the important way to classify tumors, from the point of view of should you get Gleevec, is not by: is it pancreatic cancer, is it lung cancer, is it melanoma? It is by what is its molecular signature?

I think all of the advocacy groups—I shouldn't presume to speak, but having worked with them—are of this belief as well, that whatever should be invested in going after the particular form of cancer that matters most to you and your family, there needs to be this fundamental research into the basic aspects of all cancers because these cancers share certain things in common and from a point of view of effective therapies probably are as likely to get a good treatment for breast cancer from a study of pancreatic cancer or vice versa as from focused therapy just on that.

The other part of it, where I do think advocacy for specific forms of cancer is incredibly important, is when it comes time to take those advances into the clinic and to make sure that patients, as you heard from the bill that Senator Brown is advocating and that we put through in some States like Massachusetts, about half of the States, that the barriers and disincentives for patients going on clinical research just have to be dropped.

Only 5 percent of cancer patients go on clinical trials, and you need to advocate that if your interest is breast cancer, that breast cancer patients have access to the newest strategies and drugs or we won't be able to change—whatever we have learned from

science, we won't be able to change the way that breast cancer is treated.

We can do this, as both of my colleagues up here have said. I am convinced that we have the science in hand to learn what we need to know. We need to do the science. I am convinced that we can develop therapies for these disorders. The next big question is will we get them out there in the field, where they are going to make a difference?

The CHAIRMAN. Mr. Simon.

Mr. SIMON. Senator Kennedy, FasterCures has pulled together a group of over 30 nonprofits in 20 different diseases to ask them "what is holding you back?" We put them in one room, and they usually aren't people who go to the same meetings. So you have breast cancer in with ALS patients, multiple sclerosis, and Parkinson's.

What they all found out was that all their problems were the same, regardless what disease they were dealing with. Those problems were the culture of research, lack of collaboration, lack of standards for tissue collection, lack of funding for translational research, lack of sharing of intellectual property at the right time, lack of training people for research and medicine.

It is not a disease-by-disease problem. We can't cure any of the diseases we are wrestling with, with the system we have. We need to devise a system that can cure diseases, and it will help us cure any disease. Cancer can be the avant-garde for this because cancer is one of the diseases where we know the most about the cause and the progress and what we need to be working on.

The foundation that has been laid through basic research is highly valuable, and my remarks should not at all be interpreted to be diminishing the role of basic research. But basic research is just that, it is basic. We have to build a bridge from that to the patient. That bridge is not being funded. That bridge is not being staffed. That bridge is not being rewarded.

All of these excellent ideas that Dr. Benz talks about do not get the funds they deserve. Why? Because as money goes down, the established investigators who have been getting grants for years and years want to keep getting grants. That is why the average age of someone who gets their first NIH grant is 42 years old. The average age people do the work for which they get a Nobel Prize is 33 years old.

We are wasting our human resources by the way we run our research system. When we do have breakthroughs, we need to have a flexible system that can move resources quickly into that area, and health is the last sector where we are using information technology to share knowledge.

They know more about your car when you go in with computer diagnostics than they know about you when you go into a hospital. They learn more about what goes on on the Internet everyday on Facebook than we know about what is going on in clinical trials in Bethesda. They are not sharing the information.

The CHAIRMAN. Well, I am all with you on health IT, and I make the case on that. We are all into that. But all of us can make the case that if you get additional kinds of grants for well-qualified research that we are going to do better.

The question comes back that I hear you, though, is a fundamental kind of sense that the idea that we are doing peer-reviewed research is not working? I don't know. That is the basic concept of our research here, and it has been.

Now, if that is your point, that is what I want to hear. If that isn't working, I don't know what the substitute is. I am not getting a lot from you to tell me what it is. I don't—my own sense is we are short on the—we have seen the investment. Now we have got the possibility, as I mentioned earlier in the comment, I am a strong believer this is the life science century. It is unlimited, and we are only funding whatever percent, 18 or 19 percent of the qualified grants on these kinds of issues. We all ought to do more.

The point about it is are those basic underlying grants that are going—if peer review isn't working—where we are trying to take the best in terms of researchers and scientists that have related information and knowledge about these subject matters and bringing them together to review these applications. I am sure there are a lot of things that could be corrected and improved on. If we are not for peer review, I don't know what we ought to be for, particularly if we are starting out on a new course.

Mr. SIMON. Well, let me address that, Senator. No. 1, peer review has two parts. One part is, is this proposal scientifically rigorous? The other part, which gets short-changed all the time, is, is this meaningful? Does this help patients?

If something is scientifically rigorous, then it often rises to the top of the heap even if something that is equally scientifically rigorous is next to it but has more merit, and we have to be able to do both. We have to have strong science, but we have to start asking will this help people?

The second part is the DARPA example. DARPA doesn't do it through peer review. They find a problem. They ask people to fix it. They have a project manager for 2 years, and they make a go/no-go decision at the end of 2 years. We don't do that in medicine.

The CHAIRMAN. Yes, well, that is entirely different from peer review. DARPA, I am familiar with DARPA. I am familiar with space, the going to the moon. I am familiar with those. But that is an entirely different concept than the peer-reviewed research.

Now if you are talking about getting sound science and grants that meet the best in terms of scientific capability and also have the best opportunity to have an impact to improve patients, I am with you. I am with you. I think we ought to be there. If we are not there, if that is an area that you think is missing in terms of the totality on it, I think that that does make sense and maybe we are not there. If that is what you are talking about, I think that makes sense.

I am just concerned about if we are not—getting into the questions about undermining peer review, if we start talking about that, we are talking about an entirely different kind of an approach. I don't know a lot of science or science researchers or researchers that think we ought to throw the peer review over the side.

Dr. BENZ. Senator.

Mr. SIMON. I wouldn't propose that, Senator, not at all. It is just we need to do more risky things than most peer-review committees are willing to do, and we need the money to do those things.

Dr. BENZ. Senator, if I might, with your permission, comment briefly, as someone who has been on both sides of peer review? In fact, I have a grant, and I just got my peer review score back. It is right on the cusp for funding. My view of peer review might change depending on what the council says.

I don't think the issue or the problem is with peer review. I think it would be very unfortunate if peer review, as the mechanism for evaluating the quality of the science, were replaced by something else because, like you, I can't imagine what would be better.

Peer review, like all human systems, has its flaws. Having served on study sessions, chaired study sessions, sat on the council—which is the second level of peer review, actually at several of the NIH institutes—what I can tell you is peer reviewers do extremely well and sincerely with what they are charged with doing. The problem in the peer-review system, in my view, right now is what rules and what criteria are the peer reviewers asked to evaluate?

If the primary mechanism for funding is the individual research grant in which individual productivity, individual accomplishment is a major parameter, we are going to fund things that favor individual accomplishment at probably the expense of the kind of collaboration.

I can offer you a quick example from the Dana Farber. In our strategic plan in 2003, we decided we needed to create these connections and these overlaps between the clinic and basic research and collaborations and platforms, you know, create what Steve Case might have called the wires and the wireless signals in the Internet because that is where the action is.

We did that, and we funded it. But we funded it with philanthropy, and we funded it with institutional dollars that we were able to generate from our own operations because there was no effective, at the time, NIH mechanism for funding that. It is what we ask the peer reviewers to do that I think we should examine, not the process of peer review itself.

The CHAIRMAN. This is very interesting, and I yield. I have taken too much time. We ought to try—this is very important, and we ought to try and sharpen that up, I think, if we are going down this pathway. I think these are good suggestions, and we ought to try and work with Dr. Zerhouni and others on this as well. We are, I think, interested.

Thank you very much.

Senator MURKOWSKI. Thank you, Mr. Chairman.

It gets back to the buzz word of the last panel in which everyone was talking about collaboration, and how do you take what you have learned from this study and what you have gained from this and learn and share that so that the benefit is greater? Again, just the focus on collaboration.

Ms. Moddelmog, I want to talk just a moment about your focus, your emphasis on the early detection and the screening. We know, it is clearly demonstrated that this is effective, this saves lives. This really makes a difference. Through the National Early Detec-

tion Breast and Cervical Cancer Program, we have seen so much good come out of that. Yet we recognize that only about 20 percent of the women that are eligible are actually taking advantage of that or utilizing that.

In the State of Alaska, I have had the opportunity to speak with those in the State that have the Breast and Cervical Cancer Early Detection Program and I have asked them what the problem is here? How do we get more women in for the screening? What is it that we need to do? Is it the geographical access that I talked about earlier?

One of the comments that struck me at that time was that there are women who don't want to come in for the screening for fear of the diagnosis because they know that they don't have the money to do anything once they get the bad news. Maybe if I just don't go through the screening, I don't have to hear it and I don't have to deal with it.

Then you live with that uncertainty until that uncertainty just takes over your life, and it is something that when we talk about access and we talk about the issues that prevent access and healthcare insurance and how we make that meaningful. To me, that is so incredibly sad to know that a woman would not take that step for the screening because she knows that once she hears what the reality is, she has no ability to deal with it after that.

How do we, in your opinion, deal with this? How significant is that aspect of the lack of access when it comes to early detection and screening? Is it because of the fear of the other side?

Ms. MODDELMOG. Well, you have hit on two issues that are extremely important. One is the cultural issue, which I would like to address a little bit, and the other is really the financial issue. I will start with the cultural issue because it does get back to the fact that women, a lot of times, don't want to know.

As a matter of fact, we did a study that we have just named the mortality report, and we went to the eight pockets in America that have the highest mortality rate from breast cancer to study these groups and find out what are the barriers that make their mortality rate so high.

I am sorry to report that in these areas of our country, the mortality rates from breast cancer are third-world mortality rates. They are the same kinds of numbers that you are going to find in the developing world. We went in to do a film of women, and we thought that we were going to be talking to women who were interested in trying to take care of themselves. We ended up naming the film "I Don't Want To Know" because they felt disempowered to do anything about it.

When you get back to the financial part of it, again, the Breast and Cervical Early Detection Program, it is not only that 20 percent of women are not availing themselves of it, only 20 percent of it is funded. There is a financial gap there already. On top of that, there are some loopholes in some of the States in terms of if you are not screened at the appropriate place through the CDC with the Breast and Cervical Early Detection Program, then you are not eligible for treatment in that State.

That is a gap that we have talked about on the Hill for several years now, and we have actually been able in some of the par-

ticular States to get that gap closed. There are several States in our union—probably about half, as a matter of fact—where if you don't get screened in the right place, then you are not eligible for treatment. And women know this.

You have really hit on something that is very troubling. Again, it gets back to my—really the part of the premise of the talk here is that as the science surges and as we put our efforts behind it, if we don't mindfully close the gap on disparities, our mortality rates may not change that much. Because the people who are getting care today will be the same people getting the care tomorrow.

We could close the gap on mortality with what we have today, much less what is coming up. The personalized medicine, targeted treatments, we couldn't be more excited about. Just like all politics is local, all cancer is personal. If we don't have access for the people that don't have it today, they are not going to get it when we have the fancier treatments.

Senator MURKOWSKI. Well, let me ask—and I will throw it out to any one of the three of you, or all three of you—if you are fortunate enough to live in Seattle and have access to the Fred Hutchinson Cancer Center and you have the experts there, or you are back here on the East Coast and you have access to the levels of care that you have at the Dana Farber, good for you. But what about the rest of those of us that live in the outlying areas that don't have access to these incredible facilities?

How good of a job are we doing in getting what we are learning from some of the great research that is out there into the smaller communities, where you may have one oncologist that is available for the whole community here? What are we doing to make sure that they have access to the best possible care? Or do you just have to say you have got to figure out a way financially, and everything else, your support system, to get you to where it is known that it is a better cancer treatment center? What do you do?

Dr. BENZ. Well, Senator, we know a few things that speak to your point and the need for us to do this better. About 15 percent of patients diagnosed with cancer in the United States will have their care given in something that looks, feels like an organized cancer center. It may not be quite as sophisticated and large as a Fred Hutchinson or a Dana Farber, but with quite expert care.

What happens to the other 85 percent? Where do they end up? And what difference does it make?

Well, it turns out it does make a difference, although the data are a little hard to pin down and haven't been rigorously published. There is enough persuasive data out there to suggest that your cancer outcomes, at least for particular forms of cancer that have been looked at, will be better if you are in the more sophisticated care facility. Not a surprising finding, but one that is true and says that the expertise and the availability of facilities and specialized care does matter for the cancer patient.

For the rest, a number of our cancer centers—and this is one of the efforts of the American Association of Cancer Institutes—have been looking at ways to partner with community practices, to reach out to smaller cancer centers, to try to find better ways to use the improved communication tools we have right now.

When those succeed, we do see that it has a positive impact. They are just not succeeding often enough.

Senator MURKOWSKI. Are we doing it enough?

Dr. BENZ. We are not doing it enough. There are limits on how an individual cancer center can do it because of the funding. There are barriers, even things like the Stark laws that limit how much information you can share if you do not have an economic connection between the cancer center or, say, a practice or a community hospital. You are limited in what kinds of information you can share because so much healthcare information—I know that Senator Kennedy knows this—is tied to billing information. You cannot share financials if you are collaborating but don't have a "business" relationship.

There are the issues you have heard about, put so eloquently, that even when you correct for all this, there are still these enormous cultural issues of people being reluctant to come to cancer center care. There is a belief too widespread in our community that coming to a cancer center is what you do at the end of the road, not what you do as the first, most important decision you make about your treatment for cancer. What is your first line of treatment and evaluation going to be?

We need this. I have often thought that it would be interesting to see what happens if all of the people who advertise and market on TV and billboards and in the magazines and on the Internet volunteered to use a certain percentage of their marketing to make people aware of how important it is to get their cancer screening, do their early prevention, and get to a cancer expert early in their care. We need something like that. In addition to the facilities and resources, I think we could find a way to do that. We need the patients to demand to get their care there.

Mr. SIMON. The NCI has a community cancer center program. It is a pilot program. It is a 3-year pilot, and it has about $15 million.

The problem is cancer doesn't have pilots. That program is only going to reach 10 hospitals in the United States of America over the next 3 years. It is already showing very good success in getting people into clinical trials at a rate of 60 percent, which is far above what it normally is. But you are talking about only 150 patients who were recruited. We have some good ideas. We need to expand them.

As everybody here does, I am sure, I get several calls a month to have people connected to the best cancer care. When my own sister-in-law, who lives on a military base, was diagnosed with breast cancer, there was one doctor on the military base, and it took a number of calls to get a second opinion off the base, at which point the military doctor wanted to drop her as a patient because she got a second opinion.

That is not right. In the area where they were living, there were very, very few other options. We have got to spread the cure as far as the disease is.

Senator MURKOWSKI. Thank you, Mr. Chairman. I don't have any further questions of the panel. I truly respect the dedication that each one of you have in your respective areas.

Ms. Moddelmog, I have written down your comment about the balkanization of body parts, and how that has been an inhibitor in

our real advancement on our war against cancer. It is a comment that I am going to be taking away from this hearing and will remember for a while. It has been very instructive.

Again, Mr. Chairman, thank you for your leadership on this issue.

The CHAIRMAN. Thank you all. You have stimulated, as you can tell, a lot of thinking and a lot of good recommendations and suggestions, and we will be back in touch with you, follow up on these matters.

We will keep the record open here for 10 days. We are very grateful to all of you. The committee will stand in recess.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR ENZI

Good morning and thank you for joining us today. Cancer is an important and relevant topic for discussion this morning, as cancer is the second leading cause of death in the United States and approximately 1.2 million Americans develop cancer each year. It is a devastating disease and federally funded research is critical to better understand the causes and methods to treat cancer. The more we know, the sooner we will be able to call cancer curable.

Investing in Cancer research is something that I strongly support. Hearing "You have cancer" from your doctor used to be considered a death sentence. Today when the same phrase is uttered, there is less fear and more hope. Federal research has led to remarkable advances. Nonetheless, when President Nixon declared war on cancer, no one ever imagined that 37 years later we would still have such large obstacles to overcome.

Today, we are here to discuss the challenges and opportunities we face in the 21st Century with the prevention, treatment and cure of cancer. This is a large task that the United States has initiated and I believe that we need to continue to fund research for cancer to better understand what the causes are, how best to treat each type of cancer and one day have a cure for the cancers that we were unable to prevent. While cancer research should continue, it is clear that it should not be at the cost of another disease. Congress should leave the funding decisions to the scientists and experts. That is, the funds should follow the research, and not respond to the advocacy of one disease over the other.

We have seen time-and-again examples of research that has resulted in victories for diseases that the funds were not directed to. If research entities are not able to benefit from flexible funding streams, chances are we would not have been able to capitalize on those opportunities.

To more quickly supply new therapies to cancer patients we need a functioning and modern FDA. Last year we built upon the critical path initiative at the FDA with the creation of the Reagan-Udall Foundation. The inclusion of this foundation was heralded by patient groups as an important component of the bill and as having the potential to speed development and evaluation of drugs. This foundation would develop tools to speed drug development through better disease models and tests to detect rare adverse events.

However, this research initiative has been denied the relatively small amount of money it needs to begin to work. It is hard to imagine why the majority side of the House Appropriations Committee would deny the necessary $1 million for this initiative. As we think of ways to speed therapies to patients, fully funding the FDA and allowing them to move forward on cross cutting critical path research is a wise use of money.

Furthermore, I must remind the committee that victory over cancer is not just about research, but it is also about prevention and treatment. For that, we need real reform to provide better access to care for all Americans, suffering from any disease or medical condition. I have introduced a bill, Ten Steps to Transform Health Care in America, that includes the steps that I think will greatly

reduce some of the impediments that prevent patients from accessing health care. The focus of today's discussion is on research, but I want to remind folks that research is only one piece of a bigger picture—we also need to focus our efforts on prevention through early screenings and treatments. Not only should everyone have access to early screenings and treatments, but we also need to ensure that all Americans that already have health insurance are utilizing the cancer screenings available to them. These foundations are essential to effective health care delivery for all Americans.

I can imagine that cancer has affected most of the people in this room. Healthcare, and specifically preventative measures, must be a priority for every American and promoting that message through my position in Congress is very important to me. When my wife, Diana, was diagnosed with colon cancer, I was grateful for the commitment our Nation has made to biomedical research. She was able to benefit from these discoveries and treatments, while my father was not as fortunate—he passed away from lung cancer. It pained me to see my family in such physical and emotional pain while they were struggling in their battles against cancer. Yet, it reaffirmed my commitment to providing flexible Federal research dollars to support the research that was already there, rather than direct funding to a disease that was not yet in the research stages to result in a discovery or cure. I would want any other family suffering from the pain associated with any life-threatening or debilitating condition or disease to have the same research opportunities.

I look forward to hearing the views and thoughts of our panelists today. I hope to better understand where the current gaps are in our system, concerning the prevention treatment and research of cancer. I also hope to hear about the current successes we have seen with the support the Federal Government is providing today. Not only research, but legislative successes over the years have resulted in better care for individuals living with cancer. I thank the witnesses for taking the time to discuss this important issue and welcome them to this important discussion.

PREPARED STATEMENT OF SENATOR MIKULSKI

Good morning. Thank you Mr. Chairman for the opportunity to talk about an issue that has touched the lives of almost everyone in this room—*cancer*—and discuss the challenges and opportunities that lay ahead of us in the 21st Century.

Welcome to our panel of witnesses: Elizabeth Edwards, Senior Fellow, Center for American Progress; Lance Armstrong, Founder, Lance Armstrong Foundation; Edward Benz, M.D., President, Dana Farber Cancer Institute; Greg Simon, President, *FasterCures*; Hala Moddelmog, CEO, Susan G. Komen Foundation; and Steve Case, Chairman and CEO, Revolution LLC.

All of you are committed to the war against cancer dedicating your careers to finding new cancer therapies and treatments, providing patients with quality comprehensive cancer care, making personal sacrifices to be activists and advocates, and speaking for the millions of people living with cancer. I look forward to hearing your testimony and having an open dialogue about this important public health issue.

Cancer is the second most common cause of death in the United States accounting for 1 of every 4 deaths; exceeded only by heart disease. An estimated 27,000 new cases of cancer will be diagnosed this year in my home state of Maryland.

Research is the best weapon we have in this fight. That's why I fought to double funding for the National Institutes of Health from *$13.6 billion* in 1998 to *$27 billion* in 2003. Funding for the National Cancer Institute doubled at that time as well from *$2.5 billion* in 1998 to *$4.6 billion* in 2003. Since the doubling of the NIH budget in 2003, I have supported increases for NIH every year. I'm concerned like many of you that funding is not keeping up with inflation. President Bush's fiscal year 2009 budget provides the NIH with $29.5 billion flat funded at the fiscal year 2008 level. This will mean fewer advances in research and a longer wait for a potential cure for cancer.

Breast cancer is still the leading cause of cancer deaths for women 20–60 years old with an estimated 41,000 deaths this year in the United States. That's why I have fought to make sure that women's health is protected.

I created Breast and Cervical Cancer Early Detection Programs in 1991 to make sure women without health insurance have access to life-saving tests like mammograms and can get the treatment they need. I also fought to pass the Breast and Cervical Cancer Treatment Act to help these women get the treatment they need if diagnosed with breast or cervical cancer. In addition, I created the Mammography Quality Standards Act in 1992. Before this law there were no national quality standards and no inspections done. Now, when women get a mammogram they know it is safe and that it meets the quality standards.

We have made strides in the areas of cancer research, prevention, and treatment. However, there is still a great deal of work that must be done. I look forward to hearing from our witnesses today to hear about the challenges and opportunities that lay ahead of us. Each one of us can make a difference together. We can make change.

PREPARED STATEMENT OF SENATOR OBAMA

Mr. Chairman, I want to start by commending you and Senator Enzi for convening this important hearing this morning. I would also like to thank Elizabeth Edwards, Lance Armstrong and Steve Case for making the time to come to Washington to share their powerful stories and insights. We are also quite fortunate to hear the expert recommendations from Dr. Edward Benz, Greg Simon and Hala Moddelmog about steps we can take as a nation to improve the care of Americans with cancer.

As many of you know, this Nation launched its war against cancer by signing into law the War Against Cancer Act in 1971, with Senator Kennedy's leadership. Since that time, America has made tremendous strides in the war against cancer and has become a true world leader in this area. This Nation's ground-breaking "bench-to-bedside" research has led to better diagnostic tools and many life-saving treatments and cures. Equally important, because of the attention and tireless energies of cancer advocacy groups, Americans are more aware and knowledgeable than ever about this

disease and how to prevent it. We've won many battles already, with the number of adults and children surviving cancer steadily increasing every decade. This war is far from over, and the downward trend in funding for cancer research is constraining our ability to move forward.

Over the past 5 years, President Bush and the Congress have cut or frozen Federal funding for cancer, signaling a troubling change in Federal funding priorities. A recent survey by the American Cancer Society Cancer Action Network found that the vast majority of Americans, 69 percent, believe that the fight against cancer should be a top or high priority for the Federal Government, and that cancer funding should be increased. Sadly, this has not been the case.

Further, the American public believes, as I believe, that we should also prioritize research to discover prevention and early detection tools that do not yet exist for the most deadly cancers, such as pancreatic and ovarian cancer. Three in four Americans, 76 percent, believe this is extremely urgent or very urgent in the fight against cancer.

I could go on with a laundry list of statistics for you, but I won't. The bottom line is that the number of Americans being diagnosed with cancer is rising, and even today, despite many new tests and treatments, too many Americans are needlessly suffering and dying from this disease. Even as we focus on these troubling facts, we can never forget that although we talk about the "War Against Cancer," we are not just talking about the disease. We are talking about our families, friends and loved ones, those who are cancer survivors, and those that have fallen victim to this terrible disease.

Each of us has a personal story to tell about cancer, and it is these stories that touch our hearts, and keep each one of us focused, committed, and determined to stamp out cancer. Many of you know that my mother had ovarian cancer, dying just 6 months after she was diagnosed, and that is my story. As such, I stand with you today, pledging to partner with you, and doing everything possible to make sure we win this fight.

To that end, I want to mention one bill that I have introduced to help us in the fight against cancer—The Genomics and Personalized Medicine Act. I re-introduced this bill with my colleague Senator Burr in April 2007, and we have been working to move this important legislation through this committee. Researchers are already applying genetics and genomics science to identify and develop new and more effective tools for developing better cancer diagnostic tests, treatments and cures. We in the Congress need to do more to expand and accelerate work in this area, and our bill does just that. I know that a number of you have touched on the promise of genomics and I look forward to partnering with you as we move forward on this issue.

In closing, I commend and thank each of you for participating in this hearing and providing us with a better understanding of opportunities and challenges regarding cancer treatments and cures, and providing specific suggestions for direction and funding for critical research at the National Cancer Institute and other institutes and agencies. We've made many important advances, and we can't let the flawed funding priorities of President Bush stop our

progress. Increased funding will translate to increased awareness and education and research, which will lead to earlier detection, better treatments, and most importantly, cures.

All of this will lead to a new story to tell about cancer, a story about extraordinary scientific and medical advancement, about a once-feared disease that no longer threatens, and about the lives of so many patients—including fathers and mothers and sisters and brothers—that have been prolonged and saved. I look forward to telling this story, and I thank you once again for your efforts to make sure this is a story that I will tell in my lifetime. Thank you.

[Whereupon, at 11:35 a.m., the hearing was adjourned.]

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